Doctoral Dissertation
Academic Year 2018

On-demand Digital Customization

for Perfect-fit Medical Product

-Distributed Design Agent Approach

Graduate School of Media and Governance

Keio University

Jianyou Li

Keio University

Thesis Abstract

No.

Registration Number:	□ "KOU" □ "OTSU" No. *Office use only	Name:	**Jianyou Li**

Title of Thesis:

On-demand Digital Customization for Perfect-fit Medical Product
-Distributed Design Agent Approach

Summary of Thesis:

This dissertation addresses the technical and social issues that inhibit the use of digital fabrication, such as 3-D printing, in the medical field and proposes a new sociotechnical collaborative framework that includes the designer (design engineer), user (patients and demanders) and design agent (clinical practitioner) as solutions.

In this approach, the designer and clinical practitioner (as design agent) can exchange their professional knowledge to develop a special design tool and related training, and the programmable modeling language is applied to develop a semiautomatic modeling sequence of product customization. Such a tool enables the nondesigner clinical practitioner to perform design capability and play the role of distributed design agent to customize medical products for patients or demanders through digital fabrication technology on demand.

I conducted this approach in two experiments, while playing the role of medical engineer. In the first experiment, through collaboration with an orthopedist, we developed a customization system to help the doctor design a 3-D printed splint for fracture immobilization of an upper limb. In the experiment with a 3-D printed respirator, a customization system was designed to help the Infection Control Practitioner with customization of a personalized respirator for hospital employees to improve the seal between the edges of the respirator and the wearer's face.

In the results of the two experiments were as follows.
(1) A clinical practitioner can operate a digital design tool to customize designs independently after a short training. (2) The design tool can generate qualified models for digital fabrication. (3) Compared to the traditional products, the customized artifacts generated in the experiments have better performance on comfortability and function. (4) The customized products can help the clinical practitioner and users solve the problem or improve the device performance in a medical environment.

Keyword: digital fabrication, medical product, on-demand, customization, distributed design agent.

主　論　文　要　旨

報告番号	甲　乙　第　　号	氏　名	李　　建　佑

主 論 文 題 目 :

高適合医療プロダクトのオンデマンド・カスタム製造に関する研究
-分散的デザインエージェントによるアプローチ

（内容の要旨）

概要：本論文は，3Dプリンティングに代表されるデジタルものづくりの医療分野における普及に際して，現場で発生している技術的・社会的課題を整理し，デザイナーと医療従事者との協働によるデジタルものづくりを，さらに進めていくための協調設計フレームワークの体系化を行うものである。

本論文の提案するフレームワークにおいては，デザイナーは医療従事者と協働で，専門知識を交換しながら，プログラミング言語が付属したモデリングソフトを利用し，治療用装具カスタマイズの自動モデリングツールを実装する役割を果たす。この特別なモデリングツールの助けを借りることで，デジタルモデリング経験がない医療従事者であっても、患者や需要者のために医療製品をカスタマイズして提供することが可能になる。本論文ではデザイナーとユーザー(患者)の中間に立ち，デザイナーとはともにツールを開発し，またユーザー(患者)には，カスタマイズされた製品を提供する役割を果たすアクターを「デザインエージェント」と名付け，その重要性とともに理論化している。

本論文では，このアプローチに則って、骨折の固定副木と医療従事者用呼吸器防護具という2つの製品に対して，協調設計フレームワークの妥当性を明らかにするための実験を行った。１つ目の実験では、整形外科医とのコラボレーションを通じて，上肢骨折固定のための3D副木を医師がカスタマイズするためのシステムを共同で開発した。2つ目の実験では、医療環境労働者用の防護呼吸器に対して，呼吸器とユーザーの顔の間の密着性を改善するためのカスタマイズコントロールシステムを協働で実装した。

これらのシステムを現場で複数の医療従事者に対して提供したところ，短時間な訓練の後，CAD操作経験なしの受験者であっても，いくつかの異なるスキャンされたモデルに適合するようにプロダクトをカスタマイズし，デジタルものづくりまでのプロセスを実行することができるようになった。デジタル技術を扱うデザインプロセスに関する，技術的なギャップが排除されたことがここに示されている。また、製成物そのものに関しても，その性能評価と記録されたデザイン経過のビデオから，製品の初期的な実用性が示されている。

最終的に，デザイナーが今後医療従事者とさらに協働していくための新しい協調設計フレームワークを提案し，スキルセットおよびツールセットのガイドラインを体系化している。

キーワード：デジタルアプリケーション，医療プロダクト，オンデマンド，カスタムメイド，分散的デザインエージェント

博士論文

On-demand Digital Customization for Perfect-fit Medical Product

-Distributed Design Agent Approach

by

Jianyou Li

慶應義塾大学

政策・メデイア研究科

指導教員 田中 浩也 教授

李 建佑

平成31年1月

On-demand Digital Customization

for Perfect-fit Medical Product

-Distributed Design Agent Approach

by

Jianyou Li

Certificated by:

Dr. Hiroya Tanaka

Professor, Graduate School of Media and Governance,

Dissertation Supervisor

Dr. Daijiro Mizuno

Associate Professor, Graduate School of Media and Governance

Dr. Fumitoshi Kato

Professor, Graduate School of Media and Governance

Dr. Masaya Nakamura

Professor, School of Medicine.

Dr. Shoko Miyagawa

Associate Professor, Faculty of Nursing and Medical Care.

Abstract

This dissertation addresses the technical and social issues that inhibit the use of digital fabrication, such as 3-D printing, in the medical field and proposes a new sociotechnical collaborative framework that includes the designer (design engineer), user (patients and demanders) and design agent (clinical practitioner) as solutions. In this approach, the designer and clinical practitioner (as design agent) can exchange their professional knowledge to develop a special design tool and related training, and the programmable modeling language is applied to develop a semiautomatic modeling sequence of product customization. Such a tool enables the nondesigner clinical practitioner to perform design capability and play the role of distributed design agent to customize medical products for patients or demanders through digital fabrication technology on demand.

Background

Along with the widespread increase of Fab Labs and the maker movement in recent years, digital fabrication technology has become more accessible to people in widely available personal fabrication at an affordable cost. The medical field also benefits from the technical popularization, especially in orthopedic, surgical and physical medicine and in rehabilitative and assistive technology. In these fields, many customizable medical devices applied to the human body are realizable with digital fabrication. Furthermore, the implementation of 3-D scanning and existing medical imaging technologies provide precise 3-D anatomic models for digital landmarks and have become critical factors for improving the fit quality for customized devices.

Question

However, the high digitalization of customizing workflow brings the challenge of digital design to medical applications, and the digital design technique and professionals of CAD are necessary in the process of designing medical devices. This technical gap contributes to more complex digital customization, implying that the clinical practitioner cannot apply this process alone. The research question is as follows:

How can the distribution of medical device digital customization be realized by new tools, roles and process in a closer collaboration?

Method

I submit a collaborative design framework for a local medical engineer and clinical practitioner to develop a specialized digital design tool that enables the clinical practitioner to overcome the technical gap of digital design and perform the role of design agent in customizing perfect-fit medical products. In the beginning of the collaboration, the medical engineer studies the product function, customizing requirements, landmark principles and operative limitation of CAD skill of the clinical practitioner and combines the advantages of digital fabrication into the design workflow. The digital design tool is a semiautomatic model generator that is constructed by the programmable modeling language in a CAD context, and the tool's interface and landmark method can be customized to accommodate the design agents' limited CAD capability.

A quick training and design exercise are formulated for the design agent to gain familiarization with the customization task, and a method that can visualize the design agent's behavior in the design exercise is developed to evaluate the design tool, design agent's performance, and training content. With the assistance of the design tool and the vantage point that connects to multiple demanders, the design agents can form a distributed fabrication network of digital customization and deliver design service efficiently.

I conducted this approach in two experiments, while playing the role of medical engineer. In the first experiment, through collaboration with an orthopedist, we developed a customization system to help the doctor design a 3-D printed splint for fracture immobilization of an upper limb. In the experiment with a 3-D printed respirator, a customization system was designed to help the Infection Control Practitioner with customization of a personalized respirator for hospital employees to improve the seal between the edges of the respirator and the wearer's face.

Results

The results of the two experiments were as follows.
(1) A clinical practitioner can operate a digital design tool to customize designs independently after a short training. (2) The design tool can generate qualified models based on the design agent's landmark input for digital fabrication rapidly. (3) Compared to the traditional products, the customized artifacts generated in the experiments have better performance on comfortability and function. (4) The customized products can help the clinical practitioner and users solve the problem or improve the device performance in a medical environment.

Contribution

The main contribution of this research is the collaborative framework whereby a medical engineer can cooperate with a local clinical practitioner to develop a digital customization workflow for a specific medical product and a responding digital design tool to enable the clinical practitioner to execute the customized task independently. Through prior study with the clinical practitioner, the engineer can define the product features, customize the steps and 3-D scanning solution with the practitioner to ensure the product feasibility and eliminate the technical gap for the clinical practitioner. From the observation to the design agent's visualized behavior in the design exercise, the medical engineer can track where the operative fault occurs and improve the design tool or training directly. Such an approach can help the medical engineer develop other product customizations for the clinical practitioner's needs.

Contents

6 Experiment

7 Analysis

8 Evaluation

9 Conclusion

List of Figures

List of Tables

Terminology

- Actor-Network Theory: A theoretical and methodological approach submitted by Michel Fallon and Bruno Latour to social theory where everything in the social and natural worlds exists in constantly shifting networks of relationship.
- Clinical practitioner: In this research, it refers the licensure clinicians or professionals who involves the fabrication of medical devices, include orthopedist, therapist and technician.
- Design agent: A kind of professional, mechanism or software can perform design for other people.
- FDM: Fused deposition modeling, or Fused Filament Fabrication (FFF), is an additive manufacturing process that deposits melted material in a predetermined path layer by layer.
- FDA: Food and Drug Administration, a federal agency of the United States Department of Health and Human Service, FDA is responsible for protecting and promoting public health.
- FEA: Finite element analyze, FEA is the simulation of any given physical phenomenon using the numerical techniques, and it also often referred to as finite element method (FEM).
- Interpolate Curve: A method of drawing curve in CAD software by inputing through points to define a curve.
- ISO-10993: The set entails a series of standards of evaluating the biocompatibility of medical device. These documents were preceded by the Triparties agreement and is a part of the international harmonization of the safe use evaluation of medical devices.
- OSHA: Occupational Safety and Health Administration, a federal agency of the United States that regulates workplace safety and health.
- Patient-Matched Device (PMD) : PMD refers the medical devices that designed and created according to the patient’s anatomy precisely.
- Quantitative Fit Test (QNFT): A type of respirator fitting test that measure actual amount of leakage into respirator fit by a machine numerically.
- Qualitative Fit Test (QLFT): A type of respirator fitting test that evaluates respirator by user’s sense of taste/small to irritant to detect the leaks.
- Respirator: A device designed to protect the wearer from inhaling particulate matter including airborne microorganisms, fumes, vapours and gases.

- Splint: A device used for support or immobilization of a limb or spine. It can be used in multiple situations, including temporary immobilization of potentially broken bones or damaged joints and support for joints during activity.
- Visual Programming Language (VPL): Programming languages that lets users create programs by manipulating program elements graphically rather than by specifying them textually.

Chapter 1
Introduction & Overview

1.1 Background

Personal fabrication and the challenge of digital design

Along with the widespread increase of Fab Labs and the maker movement in recent years, digital fabrication hardware, such as 3-D printers, laser cutters, or Computer Numerical Control machines, have not only been applied in industrial companies or operated by expert staff but have spread to community factories and home garages, where the impact, size, and reduced cost of these machines have made them more accessible and user friendly to most people. Since the popularization of personal computers in the 1990s, which promoted personal creativity with audio/video, text publication and graphic content [1-3], leading to today's so-called "Self-media," desktop manufacturing hardware that offers various approaches to production and differ from approaches of mass manufacturing and supports the movement by people to "Self-producer/Maker." Because personal fabrication is not limited by the cost of injection molding and production quantity, it can realize special types of productions, such as on-demand production, one-off production, and customization to serve an ignored segment of the market or a demander[1] that cannot offer enough profit for mass production [4,5].

[1] By demander, who are potential customers with very diverse or personal requirements for a product, but cannot form a niche market worthwhile for investment in a product by a manufacturer.

Such production requires both digital fabrication hardware and digital design capability [3]; however, the popularization of digital fabrication hardware enables the self-producer/maker to obtain fabrication autonomy but not design autonomy. The digital design capability allows modeling of 3-D geometries of expected objects in the context of CAD and generating necessary data for digital fabrication; it also requires the operative technique of commercial CAD software and professional training in the design of complex parts and structure.

Although digital fabrication machines have become more user friendly in recent developments for nonexperienced makers[2], there is no shortcut for mastering digital design capability. Simplified CAD designed for beginners has been developed to solve this gap, but the reduced learning period of CAD software does not mean the software can help the maker build complex, efficient, and precise 3-D objects. If makers cannot acquire the capability to create digital design content for fabrication, their production will be limited to duplicating objects provided by others in open sources.

Digital fabrication of a medical product

Medical care is essential for modern life quality, and it is also a highly developed field in the digital fabrication industry. In the development, environment, and user groups of medical products, challenges and opportunities exist for digital fabrication. With the recent growth in the availability of digital fabrication hardware, the medical field also has benefitted from this technical popularization, especially in orthopedic medicine, surgery planning, physical medicine, dental medicine, and rehabilitative and assistive technology. Although precise medical product manufacturing relies on an industrial/ medical level 3-D printer, low-cost 3-D printers offer the opportunity to incorporated those applications limited by their high cost in traditional solutions and stimulate further innovative attempts.

From the literature, the medical applications of digital fabrication mainly focus on the customized artifacts that are applied to the patient's body for treatment or for assistive or protective purposes, such as traditional splints, prostheses, scoliosis braces, assistive devices and personal protective devices as shown in Fig. 1.1. The user can be a patient, clinical practitioner or related individual who works in a medical environment or contacts patients. Such a product is required to be perfectly custom-fit to the user's body to achieve the necessary function. For example, the splint has to be cast along the affected limb to support or immobilize the joint, and a prosthesis has to be tightly fixed on the remaining part of the limb to extend the patient's movement. These cases are

[2]Refer to the attenders in the maker culture who widely apply open-source manufacturing hardware, electronic component and digital design for personal fabrication and creation.

typically customized products that are made based on demander needs and improve one's life or job through customized fit, function and performance [7,8]. Due to the unique fit and above features, a customized product only matches and works for one specific user. Therefore, such customization equips both characteristics as below and is suitable for digital fabrication applications:

(1) **On-demand manufacturing:** The product cannot be prefabricated without a clear requirement and can only be produced on demand by a specific user.

(2) **One-off production:** The product's design is not compatible with other users, and the product is usually only produced once for a specific user.

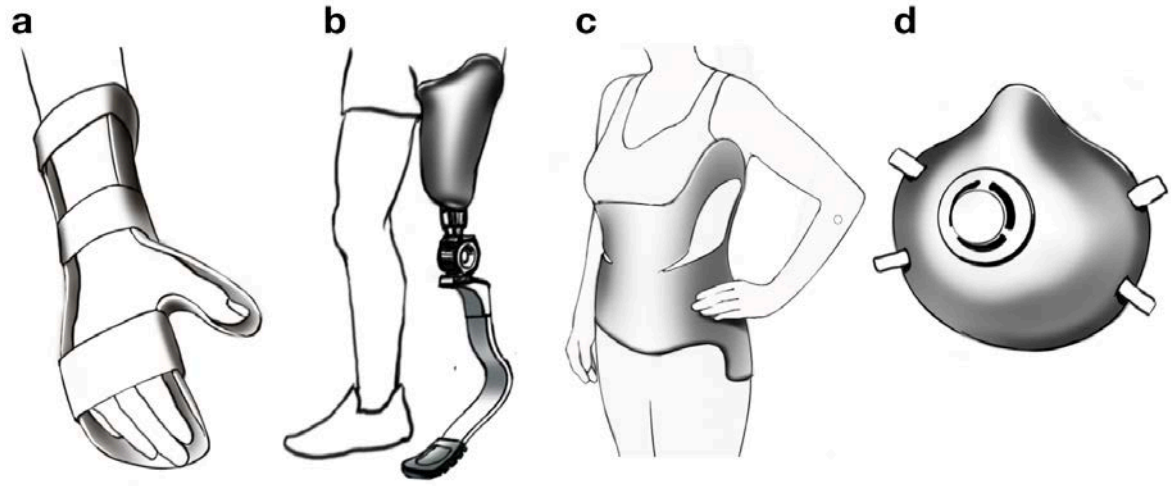


Fig. 1.1 Traditional customized medical devices. **a**. Forearm splint made by thermoplastic sheet. **b**. Lower-limb Prosthesis for sportsman. **c**. Scoliosis brace. **d**. N95 Particulate Respirator.

Traditional customization of a medical product

Before the advent of digital fabrication, these customized products were made by hand or acquired from ready-made products. However, the ready-made product is limited on the standardized model of mass production, and the design is based on the median of anthropometric measurement to match the most users possible. Certainly, the product does not suit those few demanders, who have diverse requirements as the target users.

In handmade artifacts, the clinical practitioner has to apply the formable material along a patient's body to cast the mold for the product's final shape directly; for example, plaster or thermoplastic sheets are frequent materials in these applications. The casting process is usually a series of complex steps and irreversible processes (Fig. 1.2). This handcraft process requires a patient's cooperation and may cause various distortions by

many factors, so the regenerated quality is very dependent on the clinical practitioner's skill and the object shape. In addition, the human body is soft, flexible, and living, and it changes gradually every day; therefore, wearing an artifact on the body for the long term may cause skin abrasion, itchiness, sweating, pressure point and other uncomfortable issues. These issues increase the difficulty of customizing perfect-fit products.

Fig. 1.2. Traditional manufacturing process of an ankle-foot orthosis that introduced in the book, Orthotics and Prosthetics in Rehabilitation, wrote by Michelle Lusardi, Miller Jorge and Caroline Nielsen, 2007.

Digital customization of medical products

Currently, digital fabrication hardware combines digital design and anatomic imaging technologies into a digital customization workflow, as shown in Fig. 1.3, and has the potential to replace the traditional customization method of the medical device. The 3-D laser scanning and other existing medical imaging technology can extract anatomic surface data precisely without contacting the patient's effected limb and can provide the

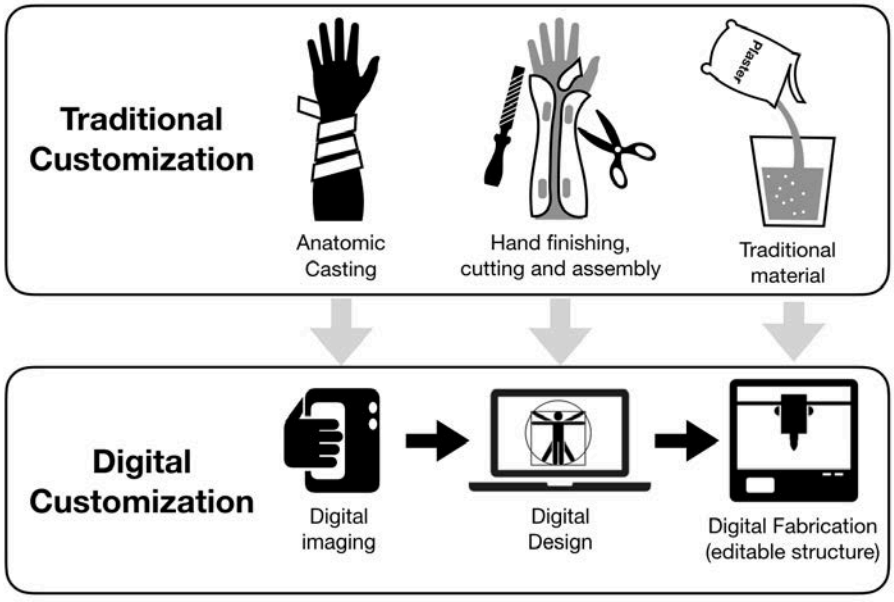


Fig. 1.3. Comparison between the traditional and digital customizations.

necessary 3-D basis for following digital modeling to create a perfect-fit object that matches the patient's body. The digital design stage allows the clinical practitioner to execute a design task, including the cutting shape, generating the thickness, and adding structure for assembly. The 3-D printing technology replaces traditional formable materials and personal handcraft to materialize the physical product and structure automatically. Such digital customization brings the digital revolution to the traditional customization of medical product based on the hand-manufacturing era.

However, the high digitalization of this customization workflow brings a technical gap to the clinical practitioner to similar to the one in personal fabrication. In the digital design stage of many studies, the modeling is operated by manual operation and requires a professional skillful in commercial CAD software and trained for designing complex parts and structure. In comparison, current 3-D scanning and 3-D printing equipment can be taught in a short time, with the digital design task being the most difficult and irregular among the three stages. If a clinical practitioner cannot hold the digital design technique and knowledge themselves, the gap will seriously limit the feasibility and efficiency of digital customization in medical applications.

1.2 Toward distribution of design and fabrication

Regarding the growing diffusion of digital fabrication and personal fabrication, at their core is the promotion of autonomy of design and fabrication for all people, endowing them with the freedom to create almost everything by their own needs. The liberation of fabrication has shown great progress recently, but design is still struggling to overcome the gap formed by the current tools and necessary knowledge. The premise of digital customization is the distribution of design and fabrication because customized product for a specific user is costly or difficult to acquire from an existing source. The maker has to integrate design and fabrication capabilities into the working process.

In the above sections, I connect personal fabrication with medical devices because they share some common points. They both have benefit from the diffusion of digital fabrication but are also limited by the digital design tool. In addition, customization is the major application for them, especially for the medical product, and digital customization technology improves the medical care quality and performance for the patient and the medical staff. The ability of the clinical practitioner to operate digital customization independently as they control traditional materials by hands in the treatment, rather than relying on other professionals, is critical. Such autonomy implies many advantages; if clinical practitioners can operate digital customization on their own, it means they obtain an operable and powerful tool to respond to inherent issues of a medical task and environment. This ability saves time, communication, and confirmation between them and the medical engineer, thereby improving the

customizing efficiency, especially the iterative prototyping and finetuning that is very common in the customization process.

Therefore, I submit the main research question:

How can the distribution of medical device digital customization be realized by new tools, roles and process in a closer collaboration?

I review and analyze medical applications of digital fabrication from the literature and involve digital design techniques to support my hypothesis as Fig. 1.4, the designer and clinical practitioner can exchange their professional knowledge to develop a special design tool and related training, and the programmable modeling language is applied to develop a semiautomatic modeling sequence of product customization. Then I discuss possible CAD approaches and collaborative frameworks between clinical practitioners and medical engineers to develop a specialized digital design tool for digital customization.

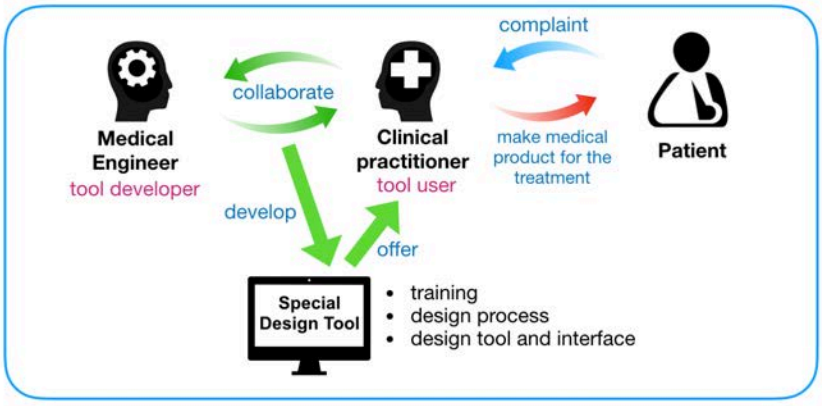


Fig. 1.4. Collaborative framework of digital customization consisted of medical engineer, clinical practitioners and special design tool.

1.3 Research objective

Several terms used in the dissertation title imply that prefabrication and compatibility with other users[3] of the medical product that serves as the focus of this research is impossible; therefore, the standardized product of mass manufacturing is excluded here. *On-demand* indicates that the timing of the user request is unpredictable, and demand content varies with the user's need and is never repeated. *Perfect-fit* means the medical product is designed according to the specific user's partial anatomy, and it matches the body perfectly to achieve its medical purpose. That definition also implies medical imaging technology is adopted to collect measurements of the body surface, which are

[3]Here, the user of a medical product is not limited to the patient; the clinician and other staff are included in the definition of a user.

then converted into digital data. Based on the above conditions, the medical product's fabrication is premised on digital customization.

The definition of clinical practitioner here refers to clinicians who apply digital fabrication technology to customization of a medical device but lack digital design capability. From the related studies of medical applications based on digital fabrication, the medical devices mainly focus on various orthosis, orthotic and assistive devices [11-13], and the targeted clinical practitioners include orthopedists, therapists, and prostheses technicians who prescribe and make medical product. Furthermore, because digital fabrication applications are emerging in the long-term care and nursing practice, such as customized daily necessaries, care products, and personal protective devices, the nurse and caretaker are also the potential device makers and are included in our scope of clinical practitioner.

This research focuses on the design distribution of digital customization for clinical practitioners and aims to submit a collaborative framework between clinical practitioners and medical engineers to develop a special digital design tool for customizing a medical device. The objectives as follows:

- The goal of this research method is developing a simple design tool that can be learned and operated by a clinical practitioner who does not have deep CAD experience after a short training.
- The digital design tool developed in the method is supposed to have integrated all necessary design tasks in it, including the incorporation of scanned anatomic surface data, the generation of structure, and the output of final data, thereby enabling the clinical practitioners to complete the customizing work efficiently by themselves.
- The method details a series of steps about how the clinical practitioner and medical engineer develop the design tool from the interview, 3-D printed prototype, software interface, training formulation and user evaluation.
- This research aims to formulate the development of digital design tool as a standard process of digital customization workflow and can be applied on other medical products that require customization.

1.4 Dissertation outline

In Chapter 2, a literature review is conducted to examine recent applications of digital customization on various medical products, the involved digital design techniques, anatomical data acquisition, software and their strategies. From this analysis, I infer two main patterns and causes of the gaps that exist for clinical practitioners. To resolve this gap, I study the relationship of a medical engineer and clinician from the various

viewpoints of FDA policy, digital design technology, and traditional customization of medical products in Chapter 3. Subsequently, Parametric Modeling is suggested as a breakthrough point for developing a special design tool for the clinical practitioner.

The development of the design tool requires a close collaboration between a clinical practitioner and medical engineer, who complement one another with their knowledge of medical devices, digital design and fabrication. The collaborative framework, their roles, skill and tool requirements are introduced in Chapter 4. The detailed methods and guidelines for developing digital design tool, workflow and training formulations are described in Chapter 5.

Two field studies of products that could be developed through small group collaboration were performed in this research: an upper limb splint for fracture immobilization and a respirator for healthcare workers. The methods are described in Chapter 6, and the results are described in Chapter 7, including the generated models and prototype fabrication. In Chapter 8, the product evaluations are described, including the training and performance of a design agent; in addition, an FEA test and fitness investigation are provided for prototypes. The contributions and discussion are described in the last chapter.

Chapter 2
Related Researches

2.1 Introduction

Since digital design is one of three essential stages in the digital customization of medical device, in this chapter, I investigate the importance of the depth of digital design by conducting a literature review of twenty studies to understand what digital design techniques and software were required in those studies and possible gaps that exist for implementation by medical professionals.

In recent decades, digital fabrication technology has grown in various medical applications related to customized devices, include upper-limb splints, ankle-foot orthoses and prosthetic sockets, and positive feedback was obtained regarding the feasibility and the various evaluations. Through 3-D scanning and printing technologies, these medical devices can be highly customized through digital workflow to improve the performance according to comfort, weight, waterproof ability, and hygiene. For the clinical practitioner, the traditional customization of these medical devices has started moving from labor-intensive hand-manufacturing techniques to digital fabrication.

However, in the workflow of digital customization, unlike simple tasks, such as 3-D scanning and printing, the digital design stage involves complex formal composition and geometric modeling. In addition, clinical practitioners usually do not have any experience in digital design, and predictably, the gap caused by digital design will become an obstacle for them when customizing devices by digital fabrication technology. Therefore, the goals of this literature review are as follows:

1. Investigate the role and importance of digital design in these customized devices, and determine what advantages are achieved by these digital design approaches compared with traditional customization.
2. Evaluate the technical gap caused by the digital design stage for clinical practitioners and the researcher attitudes toward applying the digital design, whether the researcher is aware of the gap, and how they reduced it for clinical practitioners.
3. Compare the advantage and shortcomings of these different approaches to reduce the gap.

2.2 Method of investigation

Due to the rapid growth of digital technology applications on medical devices, many relevant publications exist in the literature to support the fields of orthopedic, rehabilitative, and physical medicine; medical engineering; and assistive technology during recent years. Several literature reviews examine the development and review the methodology [14-19]. The articles in the literature pool of this review are collected by searching keywords combined from three main technologies: medical devices, digital fabrication and anatomical data acquisition. The keywords related to medical devices are splint, prosthesis, orthosis, brace and assistive device; the keywords related to digital fabrication are 3-D printing, AM/additive manufacturing and rapid prototyping; and the keywords related to anatomical data acquisition are CT/computed tomography, MRI/ magnetic resonance imaging, 3-D scanning and anthropometry. Some articles are identified from the common references of the searched articles. Because the investigation purpose focuses on how digital design affects the clinical practitioner and customized device, five exclusion criteria are applied to filter the collected literature:

- Customizable device: The device and its design process proposed in the research must be related to a customizable and custom-fit device because a standardized device can be prefabricated as a ready-made product without the clinical practitioner's adjustment. Many open-source, fixed-design prostheses were excluded for the same reason.
- Anthropometric measurement: Any kind of anthropometric measurement is required to be a condition to filter these studies, and the result of the measurement should be the input that affects the following device design result. In addition, the measurement is not limited in 3-D scanning or medical imaging technology, and other measuring approaches can be regarded as the researcher's strategy to overcome the gap of digital design.
- Surgery planning: Much of the literature applies CT or MRI to acquire the 3-D model of organ, muscle and bone, and materialize them as physical objects by 3-D printer for surgery simulation or evaluation. However, their main output duplicated a scaled model from medical images directly, and no digital design stage and tool are involved to create an applicable device. This type of literature is not within the scope of this study.
- CAD details: Because this investigation collected detailed information of digital design as possible, those articles with detailed descriptions of CAD software, steps and commands in their methods are preferred.
- Diversity of approaches: Most literature focused on ankle-foot orthosis (AFO) and an upper-limb splint. To consider diversity in approach, the literature for different

customized medical devices applied to other anatomic parts are included in my review.

After filtering the literature, the search identified 20 articles [20-39] for the following analysis. A timeline of reference years is organized in Fig 2.1 to explain the excluded references, the references that fall into the scope, and the key references defined in the filtering process; the timeline also presents the transfer of the research focus from the feasibility of digital fabrication of medical device to digital design stage of the device.

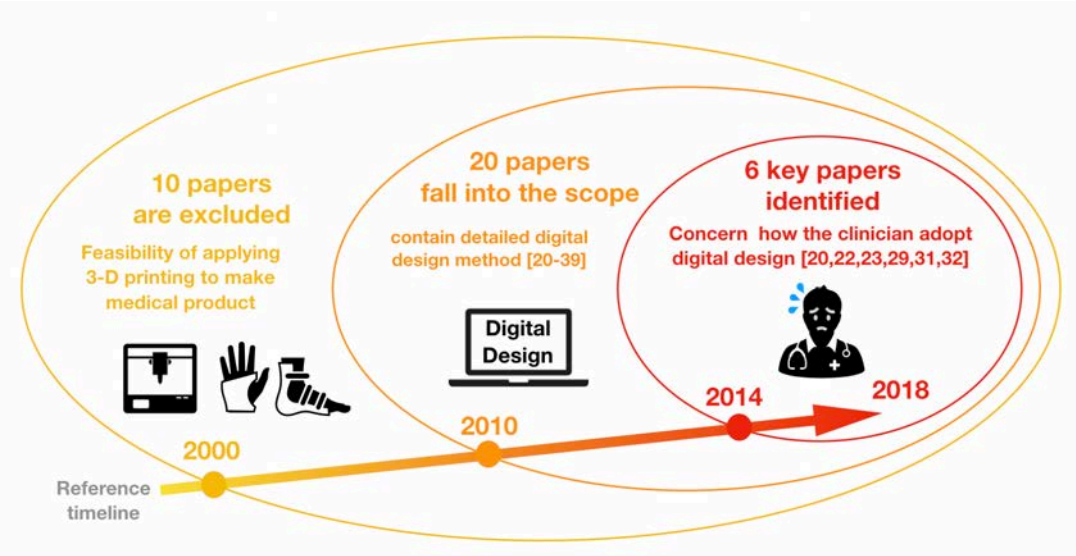


Fig.2.1 . Timeline of reference years of customizable medical device.

1) Excluded references: The 20 articles were published after 2010; 10 earlier articles are excluded. Those excluded articles mainly focus on the manufacturing method, mechanical feasibility and evaluation of physical medical devices made by digital fabrication technology; these articles do not contain sufficient details about the device's digital design method because their priority is the feasibility of digital fabrication a manufacturing alternative for these devices.
2) References fall into the scope: After the digital fabrication technology had proven its feasibility in making medical device in the previous period, the references after 2010 provide clearer processes and used CAD tools about how the devices were designed in their methods; furthermore, they present the situation of available tools and discuss possible technical problems that occur during design practice. In addition, the digital anatomic model acquisition became an important condition to realize a perfect-fit device in the digital design stage, and the shortcomings of the different methods of acquiring anatomic model and solutions are discussed deeply in these articles.

3) Key references: After the real situation of digital design techniques applied in designing medical device became more concrete from these references, some articles, such as [20,22,23,29,31,32], further address the feasibility of introducing these design techniques into the clinical environment, especially whether clinicians can adopt these CAD tools and workflow and stably utilize them in the clinical practice. These key references concern this issue, and strategies for solving it are developed.

I list several classifying indicators that are applied in Section 2.3 and explain their meanings to evaluate the difficulty of digital design for the clinical practitioner.

- Device type: These articles are classified into several frequent device types, and the type indicates the medical function, anatomic contact area and design complexity.
- Modeling approach: For example, manual modeling means clinicians are deeply involved in the complete operation. Parametric modeling implies an existing model or model pattern is created by other engineers, and clinicians can modify the model by parametric input without rebuilding the model.
- Source type of anatomical data acquisition: The source includes 3-D scanning, medical imaging and other anthropometric measurements, and the source type indicates the data complexity and how it is applied in customizing the device. For example, a 3-D scan catches more details than the physical measurements that acquire limited size parameters, and CT or MRI can capture more complex data, including for internal bone and muscular structures, then a 3-D scan.
- Software used in the process: In some articles, three or four software programs are applied in the process to solve the different issues. Of course, more software involvement implies that clinicians need to learn more interfaces and operative logics, and steps of data conversion between the different software.
- CAD command keywords: The command keywords are recorded from the method description and figures. More commands mean more CAD operative steps and more difficulty for clinicians. Some complex commands include more than one step; for example, the subtraction Boolean usually includes how and where to arrange the mass geometric objects on the target body for subtraction.
- Difficulty: The difficulty of digital design stage for clinical practitioner is based on how many software programs are involved, how many commands are required in modeling and the complexity of the generated devices.

2.3 Classification

2.3.1 Summary

Of the filtered articles, most focused on ankle-foot orthoses or an upper-limb splint, and the percentages are marked in Fig. 2.2. Some articles on wrist-palm splints are separated from the group with the upper-limb splint with respect to their prototypes and applications in the figures. Many studies on noncustomizable prostheses are excluded, and only the scalable prosthesis is qualified for inclusion. The 20 articles are organized according to the results, as shown in Table 2.1 [20-39].

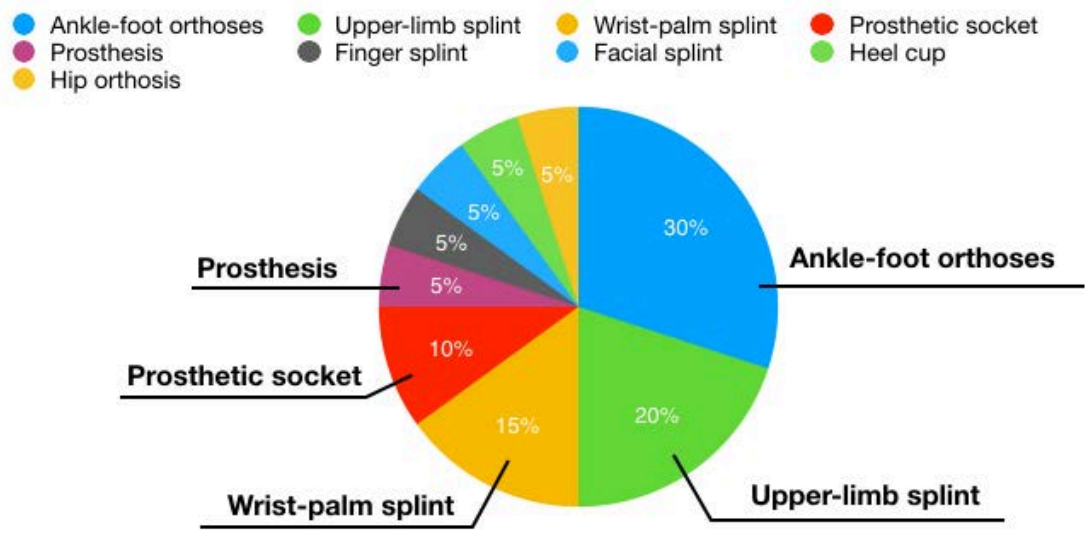


Fig. 2.2 Pie Chart of device types classification.

Table.2.1 Investigation summary of digital design approaches in the references.

Refer no/ 1st Author/ Year	Device type	Modeling Approach	Anatomic data aquistion	Applied CAD Software	CAD command keywords	Reference type	Diffi-culty
[20] Zuniga 2017	Prosthesis hand	scalable model	photo-grammetric	• Blender • MakerWare	Plane, calibration, Scale.	Journal/ BMC Research	Easy
[21] Strömshed 2016	Prosthesis arm socket	manual modeling	3D scan	• Meshmixer	trim, thicken, adjust plane, scale, offset.	Thesis/ Lund University	Middle
[22] Takekoshi 2016	Wrist-palm splint	parametric model	physical measure-ment	• Rhino • Grasshopp er	input parameters, bake	Technical report/ IPSJ 情報処理学会	Easy

Refer no/ 1st Author/ Year	Device type	Modeling Approach	Anatomic data aquistion	Applied CAD Software	CAD command keywords	Reference type	Diffi-culty
[23] Paterson 2014	Wrist-palm splint	parametric model	3D scan	• Geomagic • Rhinoceros	trim, smooth, offset, lattice	Journal/ Hand Therapy	N/A
[24] Mavroidis 2011	Ankle-foot orthoses	manual modeling	3D scan	• Geomagic	smooth trim offset extrude	Journal/ Neuro Engineering & Rehabilitation	Difficult
[25] Munhoz 2016	Hip orthosis	manual modeling	photo-grammetric	• MeshLab • Blender	remove, scale, trim, mirror	Journal/ Biomedical Engineering	Difficult
[26] Shin 2017	Ankle-foot orthoses	manual modeling	3D scan	• Standard Cyborg	mark bony, trim, smooth, remove, smooth	Conference paper/ 50th CIRP	Difficult
[27] Zhang 2017	Upper-limb splint	manual modeling/ algorithm modeling	3D scan	• mapping software • pattering software • FEA software	texture mapping, pattern genration, thicken FEA	Conference paper/ UIST 2017	Difficult
[28] Fitzpatrick 2017	Upper-limb splint	manual modeling	3D scan	• 3-matic • Meshmixer	patch, smooth, trim, extrude, extract, apply pattern	Conference paper/ Design and Technology 2017	Difficult
[29] Lin 2017	Upper-limb splint	algorithm modeling	3D scan	• Vascular Modeling Toolkit	clip, line, flare edge, poly-line loop, array point, sphere, boolean, line, tube, boolean gap	Journal/ 3D Printing in Medicine	N/A
[30] Baronio 2016	Wrist-palm splint	manual modeling	3D scan	• Remesh Cleaner • Rhino • RhinoResur f	fix mesh, offset, convert UV surface, extraction, thicken, boolean subtraction.	Journal/ Applied Bionics & Biomechanics	Difficult
[31] Cha 2017	Ankle-foot orthoses	algorithm modeling	3D scan	• MediACE3 D	point, line, circle, project, trim.	Journal/ Applied Bionics & Biomechanics	Easy
[32] Porting 2016	Finger splint	parametric model	physical measure-ment	• Rhino • Grasshopp er	input parameters, bake	Thesis/ Groningen University	Easy
[33] Walbran 2016	Ankle-foot orthoses	manual modeling	3D scan	• MeshLab • Creo	plane, intersect, sweep, trim, thicken, mount modeling, extrude	Journal/ Cogent Engineering	Difficult
[34] Pallari 2010	Ankle-foot orthoses	manual modeling	3D scan	• 3-matic	Complex proces	Conference paper/ 21st SFF Symposium	Difficult

Refer no/ 1st Author/ Year	Device type	Modeling Approach	Anatomic data aquistion	Applied CAD Software	CAD command keywords	Reference type	Diffi-culty
[35] Liacouras 2017	Prosthetics attachment & devices	manual modeling	CT	• Mimics Medical • Soliworks • Freeeform Pluse	draw curve, extrude, boolean union.	Journal/ 3D Printing in Medicine	Difficult
[36] Teller 2012	Ankle-foot orthoses	manual modeling	3D scan	• 3-matic • OrthoModel	Complex process	Journal/ BMC Musculoske-letal Disorders	Difficult
[37] Lim 2017	upper-limb splint	manual modeling	3D scan	Unigraphics	trim, divide, mesh, hole generation algorithm, discretization, generate sphere, boolean subtract	Journal/ Mechanical Science & Technology	Difficult
[38] Mazher 2018	Facial prosthesis	manual modeling	CT	• Mimics • 3-matic	mirror , boolean, fill gap, smooth, trim.	Journal / Virtual & Physical Prototyping	Difficult
[39] Li 2018	Heel cup	manual modeling	3D scan	• Mimics • Geomagic • HyperMesh • Abacus 2017	segment, boolean, optimize mesh, reconstruct surface, mesh operation, assemble	Journal/ Translational Medicine	Difficult

2.3.2 CAD approach study

The frequent software applied in the literature are summarized in Table 2.2. Due to the limited available literature, no specific software showed much higher frequency than others, and the software adopted is quite scattered. Rhinoceros 3-D and 3-matics have higher acceptability and can be considered as the study objects or tools examined in this dissertation. Multiple software applied in one approach is very commonly used to deal with various tasks; for example, Mimics is commonly used for converting the DICOM data generated by CT to mesh [35,38], and 3-matic is applied to generate organic structure [28,34].

Table.2.2 Statistic of frequent used software in the digital design stage.

Applied Software	Frequency (times)	Device type and reference number	Modeling approach
Rhinoceros 3D	4	• Wrist-palm splint [22,23,30] • Finger splint [32]	Manual modeling/ Parametric model
3-matics	4	• Upper-limb splint [28] • Ankle-foot orthoses [34,36] • Facial prosthesis [38]	Manual modeling

Applied Software	Frequency (times)	Device type and reference number	Modeling approach
Mimics	3	• Prosthetics attached devices [35] • Facial prosthesis [38] • Heel cup [39]	Manual modeling
Geomagic	3	• Wrist-palm splint [23] • Ankle-foot orthoses [24] • Heel cup [39]	Manual modeling
Blender	2	• Prosthesis hand [20] • Hip orthoses [25]	Manual modeling
MeshLab	2	• Hip orthoses [25] • Ankle-foot orthoses [33]	Manual modeling
Grasshopper	2	• Wrist-palm splint [22] • Finger splint [32]	Parametric model
Meshmixer	2	• Prosthesis arm socket [21] • Upper-limb splint [28]	Manual modeling

However, the involvement of multiple software implies an increase in the difficulty of CAD operation, and the unavailability of suitable CAD software is mentioned by Chen in his review article of 2016 [14]:

In the research setting, several software platforms were used to process the 3D geometry of an orthosis and a prosthetic socket. However, the current O&P[4] software cannot take the 3D scan data, modify the geometry of the 3D surface, convert the surface into a solid object, and create trim-lines. In order to achieve these in an efficient way, a software platform that is tailored for AM[5] of O&P is required.

Paterson also noted a similar dilemma of software and concern for clinician use in a study[23]:

Prior to this study, there was no specialized CAD software available for upper extremity splinting with a splinting sequence sympathetic to that of traditional splinting to ease the transition for splinting practitioners.

Most CAD software studied are not user friendly for clinicians. In Baronio's research [30], he mentioned "The use of a 3D CAD modeling software is typical in a RE environment. However, its use requires specific skills that are not that diffuse among clinicians and orthopedic/orthotics technicians."

[4] Acronym of Orthoses & Prostheses.

[5] Acronym of Additive Manufacturing.

Although some engineering CAD software that focuses on medical applications have tried to integrate different functions for these common steps, learning the software requires more time for the user. Lunsford also expressed similar exceptions and suppositions in his review article [16]:

Software for CAD has seen less of a price decrease than 3D printers themselves and can also require a high level of expertise, because raw data from 3D scanning must be manipulated to make a build file. Hopefully, these programs will become more user-friendly over time. However, regardless of how user-friendly CAD software becomes, significant training may be required for individuals to use such programs in rehabilitation endeavors.

In addition to the software, the statistics of the CAD commands appearing in the method is another important indicator of the difficulty involved in applying digital design. Many articles that apply manual modeling and mass commands are classified at the Difficult level because the manual modeling process is too long to learn and execute for the clinical practitioner. Several common CAD commands are identified from methods described in the literature. For example, “offset”, “extrude” and “thicken” are used to create a solid shell attached to the contact area, and “smooth” frequently appears to optimize the sharp edge after trimming or on a low-quality surface. These commands are common and necessary to generate a perfect-fit shell based on the rapidly scanned area on a patient’s body, as shown in Fig. 2.3 [24,31,39]. A command usually requires several steps, such as clicking an icon on the toolbar and inputting the required data, and every command uses different logic to interact with the software, and clinicians have to

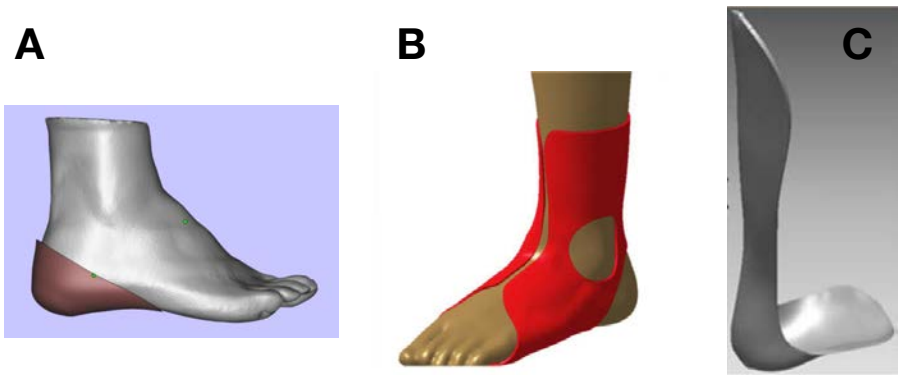


Fig. 2.3 Device shells adopted in references. **A**. A heel cup designed by Lan Li, Longfei Yang, Fei Yu , Jianping Shi, Liya Zhu, Xianfeng Yang, Huajian Teng, Xingsong Wang, and Qing Jiang in the paper “3D printing individualized heel cup for improving the self-reported pain of plantar fasciitis.” published in Journal of Translational Medicine. 2018(16):167.[39]. **B**. Ankle-foot orthosis designed by Yong Ho Cha, Keun Ho Lee, Hong Jong Ryu, Il Won Joo, Anna Seo, Don-Hyeon Kim and Sang Jun Kim in the paper “ Ankle-Foot Orthosis Made by 3D Printing Technique and Automated Design Software.”, published in Journal of Applied Bionics & Biomechanics. 2017;2017:9610468. [31]. **C**. A piece shell of Ankle-foot orthosis designed by Constantinos Mavroidis, Richard Ranky, Mark Sivak, Benjamin Patritti, Joseph DiPisa, Alyssa Caddle, Kara Gilhooly, Seth Sivam, Michael Lancia, Robert Drillio and Lauren Govonil. in the paper “Patient specific ankle-foot orthoses using rapid prototyping”. published in Journal of Neuro-Engineering and Rehabilitation. 2011;8:1 [24].

remember how the software responds to give the right input. Some complex commands, such as Boolean operation, is a common method to create a ventilative structure or to indicate a reduction in weight; they also increase the lengths of the command sequence and difficulty for the clinical practitioner.

2.3.3 Approach patterns

From the result, two main patterns for equipping the different anatomical data acquisition and modeling approaches were observed:

1) 3-D scan and manual modeling: 3-D scanning is the most frequent source of anatomical data acquisition in the literature, and it is also a necessary method to provide customizing data for the perfect-fit device. It usually accompanies manual modeling, and this combination accounts for more than 50% of the literature [21,24,26-28,30, 33,34,36,37,39] because the scanned mesh model usually includes a series of steps to extract the required area by the trim command, to thicken a solid shell and smooth the edge. The manual modeling is the key factor in the creation of a comfortable socket or external shell to partially cover the user's body, but it requires deep CAD skill and design knowledge for the clinical practitioner.

2) Parametric model without 3-D scan: On the other hand, some researchers are aware of the difficulty of digital design emerging in the customization of these devices for the medical practitioner, so they adopt parametric/scalable models to avoid the necessity of manual modeling [20,22,32] (Fig. 2.4). This modeling approach uses preprogrammed or prebuilt models by a CAD expert, so clinicians do not need to deal with complex modeling. However, these models are controlled by parameters rather 3-D scan, so they adopt simple anatomical data sources to catch parameters,

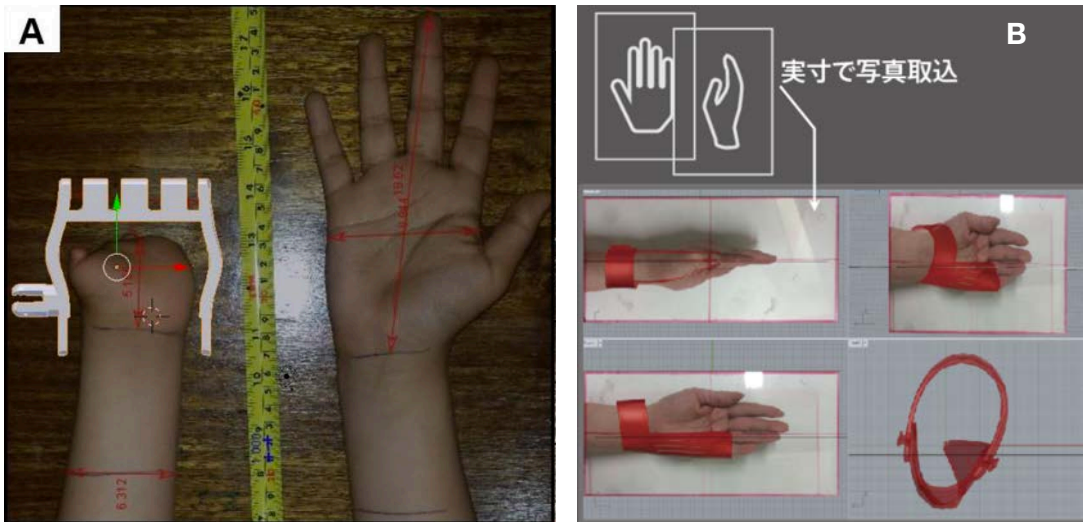


Fig. 2.4. Photogrammetric method adopted in the approaches of prosthesis and wrist splint A. The physical measurement adopted by Jorge Zuniga in the project, Cyborg beast [20]. B. The photogrammetric method adopted by Minatsu Takekoshi in her Metacast project [22].

such as photogrammetric and physical measurements. Compared to a 3-D scan, such an approach has a lower quality of perfect-fit performance.

The above 2 patterns indicate that the digital customization of medical device faces a dilemma between the high customization quality and the easy-to-use customizing tool for the clinical practitioner. The first pattern that applies 3-D scan and manual modeling can help the device to achieve perfect-fit comfort, a lighter and stronger structure and better ventilation, but it is not practical for clinical practitioners who do not have CAD skills. Although some approaches use the physical measurement and parametric model to avoid complex manual modeling and 3-D scanning, a trade-off occurs in the perfect-fit customization quality.

2.4 Findings

From this investigation, we learned digital design plays a critical role in the creation of a perfect-fit device and provides advanced structure for exploiting the advantages of digital customization; this is also why the digital design developed into a complex and professionalized task in these applications. My approach is aimed to more comprehensively cover the whole process from the development of the design tool, reactions to frequent problems, clinician's training and evaluation.

Better body scanning

The perfect-fit feature is a critical factor to offer good comfort and medical function on the device shell. Although CT and MRI can provide higher quality scanned models, they require costly equipment and complex operation; therefore, 3-D scanning is undeniably the most low-cost and rapid method to capture the anatomic model [17]. However, insufficient light or involuntary movement in the scanning process usually causes deformations or holes on the anatomic model, and these scanning flaws may fail in the following modeling steps. A rapid automatic modeling technique or sequence to fix these flaws should be developed and integrated as a part of the digital design stage.

Semi-automatic designing mechanism

The shortage of suitable CAD software for designing medical devices has been reported by some references, and diverse modeling demands are difficult to be solved with current software options. For example, the main value of digital customization that applies to these medical applications is not only the printing of a piece of shell rather than using traditional material but also in endowing the device with further advanced functions or properties that traditional handcraft customization cannot offer, such as the smart structure that improve the device's weight reduction, strength and ventilation, as shown in Fig. 2.5.A and B [27,34]. Designing these structures usually requires applying

a modeling program; however, these self-defined modeling techniques are not available in the software. In addition, an assembly solution to attach on the patient's body is necessary in most applications (Fig. 2.5 C) [21,33]. Such a functional structure is very dependent on the purposes and difficult to integrate into one software. Thus, manual modeling and multiple software are adopted in most cases.

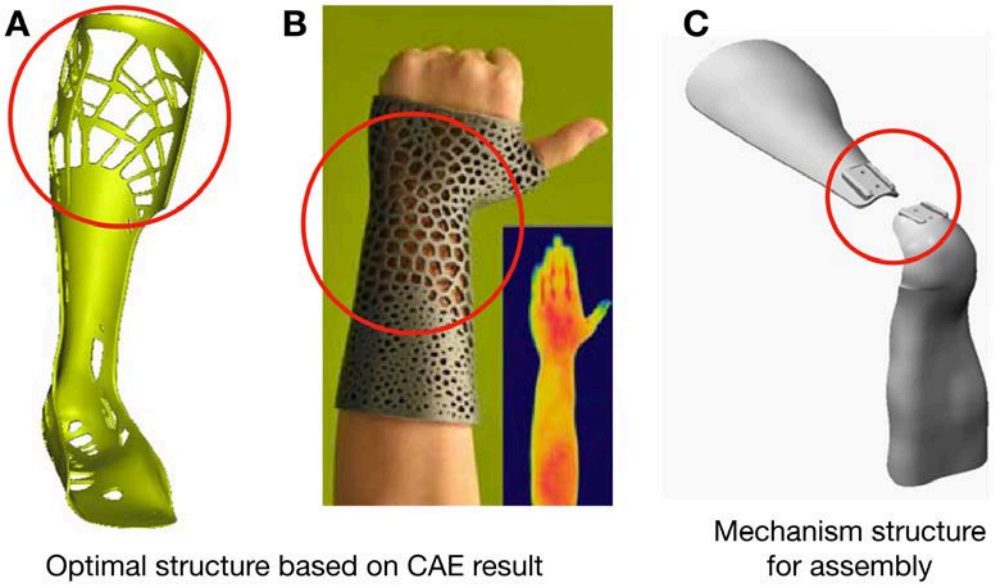


Fig. 2.5 Smart structure and functional features. **A**. Ankle-foot orthosis with the optimal structure based on FEA data developed by Pallari P, Dalgarno KW, Munguia J, Muraru L, Peeraer L, Telfer S, Woodburn J in their paper "Design and additive fabrication of foot and ankle-foot orthoses." in Proceedings of the 21st Annual International Solid Freeform Fabrication Symposium–An Additive Manufacturing Conference, page 834-45.[34]. **B**. Thermal-comfort cast with the Voronnoi lattice structure developed by Zhang X, Fang G, Dai C, Verlinden J, Wu J, Whiting E, Wang CL in their paper "Thermal-comfort design of personalized casts." published in Proceedings of 30th Annual ACM Symposium on User Interface Software and Technology", page 243–54. [27]. **C**.Ankle-foot orthosis and the socket structure on its back side developed by Walbran M,Turner K, McDaid A in their paper "Customized 3D printed ankle-foot orthosis with adaptable carbon fibre composite spring joint." published in Journal of Cogent Engineering. 3(1) [33].

Some literature mentioned the algorithm modeling approach and modeling mechanism to solve the issue of whether clinicians can adopt CAD tools to design a medical device. Some research has simulated the interface or generated a model by modeling the workflow based on a scanned anatomic model [23,31]. However, a practical program, interface, operation steps, and verification by clinicians are not proposed; therefore, a feasible semi-automatic modeling tool, its interface and training content should be developed and should be able to be practically tested by clinicians to design devices on different anatomic models in an experiment. Then, the tool's stability, efficiency and user friendliness should be further evaluated for clinicians. The operative steps and interface of the design tool should be simplified to reduce the training period as possible for clinicians, and this simplification should enable clinicians to focus on the interaction between input adjustment and evaluation of the generated designs.

Evaluation method

Due to the evaluated result of the design tool, which involves many factors at the same time and includes the interface, operation and training, the developer should identify what factor cause the device design task to fail. For example, the model generation may fail due to the program crashing or user error, and the solution will depend on the reason. Therefore, an evaluating method should be developed to detect the failure factor in the experiment via the design behavior of clinicians or other input sources, and indicate to the developer how to exactly improve the interface design, modeling program or training content. The efficiency of the software agent to help clinicians complete a printable device model is also an important indicator in the evaluation, and a rapid efficiency is expected to be improved by the semiautomatic agent. Compared to the traditional device's manufacturing process, the reversibility of a customizable device's digital design is an obvious advantage, and faster design efficiency implies that clinicians have more willingness, time and opportunity to attempt different design solutions in a short time.

Chapter 3
Design Process

3.1 Introduction

Chapter 2 reveals that medical devices made by digital customization can provide the advantages of perfect-fit features, smart structure or attached mechanism design to achieve better function or performance than traditional devices can provide. However, in the device's digital design stage, applying multiple software and complex modeling steps is unavoidable, and these tasks occupy a significant part in the customizing workflow. It creates a high technical threshold for clinical practitioners who do not have CAD experience and limits their autonomy and possibility for the device design. Along with the trend and potential of digital customization in the medical area, predictably, the development and applications will show great growth in the future and impact traditional clinical professionals when customizing devices for treatment.

The U.S. Food and Drug Administration published "Technical Considerations for Additive Manufactured Medical Devices- Guidance for Industry and Food and Drug Administration Staff" in 2017 [40]. This document implies that certificated manufacturers and their medical engineer can offer customized medical devices to patients and that also means the medial engineer will replace clinical practitioners as the alternative device maker in such a process. However, customizing a medical device is very different from designing a standardized device; therefore, in this chapter, I discuss digital customization features of medical products, comparison with traditional customization, and the medical engineer's role with regard to professional training, job duty and licensing.

Then, I discuss the possibility for clinical practitioners to adopt digital customization applications from the technical viewpoint of digital modeling. Through comparison of the two approaches, namely, direct modeling and parametric modeling, I note that the latter has the potential to compose the design tool for customizing a patient-matched device. Because of programable automation, the tool operator does not need to involve deep CAD operation; therefore, the design tool can be applied by clinical practitioners to obtain the autonomy of the customizing device. Finally, I will recommend a collaborative network consisting of a clinical practitioner and medical engineer to develop the digital design tool.

3.2 FDA guidance

Current perfect-fit medical devices are mainly customized by manual labor of licensed clinicians, therapists or technicians. They cast pure material and assembly components into devices by their hands and ensure the devices can perform correct function for patients as intended treatments. In the case of a fracture splint, an occupational therapist can execute the medical order of splinting as prescribed by the orthopedist, or the orthopedist can execute the splinting directly. However, along with the new regulations emerging, the digitalization of customizing medical device will form a new technical barrier and isolate participants of other clinical staff.

The "Technical Considerations for Additive Manufactured Medical Devices- Guidance for Industry and Food and Drug Administration Staff" published by the U.S. Food and Drug Administration in 2017 is the significant guide to the digital fabrication technology applied to medical devices, and many countries have promulgated related policies in recent years [41,42]. The guidance defines the medical device customized via digital fabrication technology as "patient-matched device" (PMD), and it shares similar process with standardized medical product. It implies the certificated manufacturers match *GMP Regulations* or *Quality System Requirements* and their medical engineers can offer patient-matched devices to patients according to the clinician's prescription and the patients' anatomic imaging data. Six parts are included in Design and Manufacturing Process Considerations, including device design, software workflow, material control, build, postprocessing and final testing consideration, as shown in Fig. 3.1.

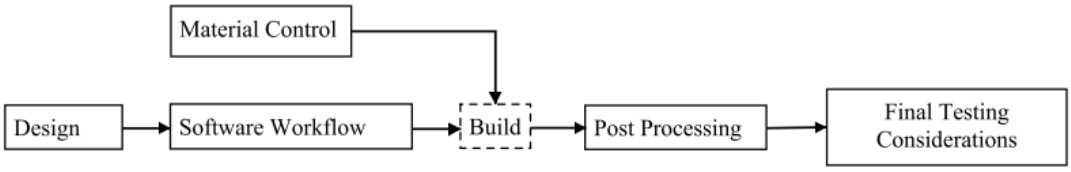


Fig. 3.1 Flow chart of the AM process in FDA guidance [40].

The PMD design is described in the device design part for a standard-sized device. As the description in Section V.B. of the guidance, the PMD designs may be modified directly by either clinical staff or the device manufacturer to make the device suit the patient, and such modification is mainly operated through the design manipulation software developed specifically for the AM device or other third-party software. Although, in the FDA guide, clinical staff can participate in the PMD design, but due to limited CAD ability and high digitalization of the device design, clinical staff cannot assess and operate the design manipulation software directly for the treatment. Therefore, in fact, the design of customized medical devices will be determined by the manufacturers and medical engineers.

In the reference investigation, many concepts of the device customizations are contributed from medical engineering areas [20,26-28,30,32,34-36,39], and they unavoidably submit various digital modeling procedures that involve complex operations in third-party software. Most software are suitable for developing device prototypes by the product engineer, rather than customizing by the clinical staff. From the overview of various specializations in the medical system, the medical engineer probably is the only professional who has enough CAD skill to complete designing the device in the digital context and will form a new technical division from traditional device customization. However, between the medical engineer and the clinical staff, many differences exist in their techniques, training goals, and job duties. I list the main difference below for later discussion:

- Clinical staff: They are responsible for traditional customization of medical devices, and include the orthopedist, occupational therapist and prosthetic technician. They are licensed staff and more experienced in applying medical devices to patients. However, CAD technique is not included in their training.
- Medical engineer: They are not directly involved in the traditional customization. Their licensure exams are not relevant to clinical treatment, but they are necessary CAD experts in the digital customization.

However, customizing medical devices is more like processing a variable treatment according to the patient’s condition, rather than simply making a standard medical product.

3.3 From handcraft customization to digital customization

In this section, I discuss the complexity and variability of the digital customization of a medical device through the comparison with traditional customization to emphasize the necessity of the clinical staff's participation in the digital customization. Then, I discuss the possible role of the medical engineer in the future digital customization based on the training, license system and job duty, and define the medical engineer's collaborative relationship with the clinical practitioner.

3.3.1 Complexity and variability of customizing a medical device

Compared to some existing medical detections, such as radiological tests and medical checks, customizing a medical device is more variable to interact with patient's anatomy and conditions. For radiological technologist or medical technologist, their tasks are to provide detected results based on the clinician's medical order for the later diagnosis, and the detection does not vary with the executor. The technologist concentrates on the operating radiologic equipment or medical detection to provide precise results, and then, clinicians can focus on the treatment based on the given result. However, customizing a device is not similar to these medical detections. In the traditional customization of a device, such as plaster splinting, a basic technique that orthopedist and therapist must provide, when applying plaster material onto the patient's body, the generated cast is dependent on the clinician's skill, experience and on-the-spot observation, and includes many technical details decided by clinicians.

Currently, the digitalization of design and fabrication brings more possibilities for the customization of a device than provided by traditional materials. The digital design stage offers multiple customizable options and design reversibility to the device designer, and it allows the designer to simulate and evaluate different solutions on digital interface iteratively. The process certainly involves many customizing decisions that rely on the clinician's subjective evaluation and judgement, and it affects the device's function and treatment performance to the patient. Therefore, the clinician's direct participation is very critical to the PMD design.

3.3.2 Medical engineer's background

Here, I discuss the medical engineer's possible role in the digital customization of a medical device based on this professional's education, job duty and license system.

Medical engineering is a multidisciplinary field integrating engineering, medicine and biology broadly, and a medical engineer applies engineering principles and material to medicine and healthcare. A medical engineer can have different names in the hospital setting; in some cases, they are called biomedical engineers or clinical engineers. Currently, no country requires that medical engineers be certified in order to perform any functions with medical technology [43]. In the United States, the Biomedical Engineering Society reports that biomedical engineers generally do not have state licensing [44]. Although some have licensing as professional engineers, no specialty exam exists for the biomedical specialty. Medical engineers' practical duties can be generally classified into two types by the contexts under which they are employed: developing products in the industry or managing equipment and devices in hospitals.

For medical engineers employed by research organizations or manufacturers, their job is to combine engineering principles with medical sciences to design and create the equipment, devices, computer systems, and software used in healthcare. For medical engineers employed by hospitals or medical centers, those responsibilities can include testing, introducing, maintaining, advising and evaluating medical equipment and devices to make sure they are working properly and safely. These tasks support clinicians by developing and maintaining medical devices in different positions, but these tasks do not directly involve treatments or prescriptions.

From the viewpoint of device development, customizing a device is very different from developing a standardized product for mass production. The device's customizing process has to be repeated in every treatment to generate devices with common functions and features, but that match specific patients. This on-demand process only occurs when clinicians can confirm the diagnosis from a specific patient's chief complaints, and customizing a device should be regarded as a treatment action rather than offering a product. Based on the training and task of the medical engineer, engineers may focus on developing the device's design in the initial stage and managing the device's fabrication and safety after prescription. Due to the lack of clinical experience and certification, collaboration with a clinical practitioner is a better method.

3.4 Parametric modeling approach

Digitalization is the main contributing factor to technical obstacles in device design but is also the potential breaking point to overcome the obstacle. In the FDA guide, the device design is mainly operated in design manipulation software to develop device models; however, most of the software found in the reference investigation are suitable for CAD experienced users.

Therefore, in this session, I refer to the features of current CAD software applied in digital customization as direct modeling, and this approach if compared with its related approach, namely, parametric modeling. Their complementarity on geometric composition inspires the idea of developing a method for a digital design tool suitable for use by clinical practitioners and developed by medical engineers.

Currently, commercial CAD software is the main tool for researchers, engineers and designers to interact with the scanned anatomic mesh, build the device model and export fabrication data [29]. However, in many studies, the CAD software has generally received a negative evaluation based on its cumbersome interface. Because the software is designed for constructing multifaceted geometric forms for manufacturing or architecture purposes, the interface displays all icons, panels and information for constructing different embryos in the initial stage. The CAD tool provides complete commands and a 3D environment for researchers to explore the process of device design; thus, they can develop stable command sequences as operable instructions for clinicians to reference. Such exploiting processes can be classified as Direct Modeling. Based on increasing numbers of approaches and prototypes, Direct Modeling approaches have provided many successful results. The modeling procedure for customizing device has become an execution of steady and continuous tasks.

However, although the model generation procedure can be archived from the fixed sequence, but the developed modeling procedure is not currently suitable for provision as operable instructions for engineer. The required time for these procedures usually ranges from tens of minutes to 3 hours, depending on the operator's skill [29,30]. Besides, many variables change and impact the customizing design in each individual design execution, such as the scanning quality, physiologic differences of anatomic limbs and patient's conditions. The engineer needs to react to these changes during modeling by modifying the input content, device features or structural parameters, and these necessary reactions challenge the stability of fixed procedures. If the model is not printable or fails based on a geometric error, the engineer must have enough geometric knowledge and skill to solve the situation. The revised solution will probably require more time and be more complex than the modeling procedure itself. These attempts at device modeling belong to an exploratory process that should only performed for study purposes; for clinical treatment, this should be shifted to a teachable skill and an efficient tool for clinical practitioner in a medical context.

On the other hand, the relative classification to Direct Modeling is Parametric Modeling, an emerging technical term in the CAD industry [45-49] that has appeared frequently for almost a decade. Direct modeling process means that the user has significant freedom to compose and modify the geometric model directly without considering build history and parent-child relationships between features [46,48].

Relative to the Direct Modeling's advantages for exploration, Parametric Modeling is suitable for combining multiple fixed tasks to generate device designs automatically. Besides, many modeling software programs can edit complex parametric models via applications of text or visual programing languages to organize modeling steps, constraints and parametric relationships [50-53]. Especially, due to its faster learning curve and visualized input/out relationship, the visual programming languages (VPL) are becoming increasingly popular in CAD applications, for example, Rhino 3D (Robert McNeel & Associates) works with Grasshopper 3D as Fig. 3.2, and Fusion 360 (Autodesk) works with a Dynamo plug-in. For reacting to variables in the customizing design and generating stable results automatically in real-time, the modeling steps should be reconstructed by parametric modeling technology and become a history-based model. Device features are well-generated by parameter-driven input, pre-defined algorithms and parent-child relationships of geometry.

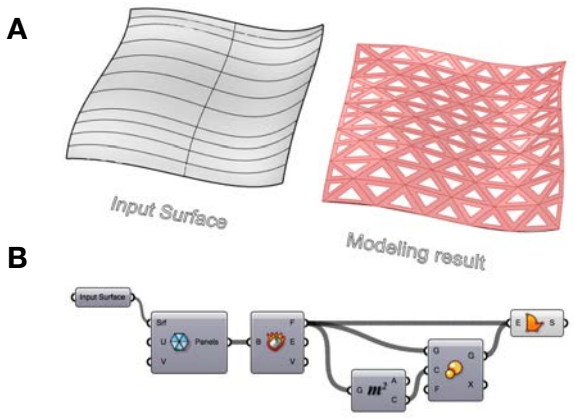


Fig. 3.2. Visual programming languages in CAD softwares. **A**. The input surface in Rhino 3D and its result after a programmed modeling process displayed in red geometric surface. **B**. The modeling program for transferring triangle meshes in Grasshopper.

3.5 Collaborative relationship

I discuss the patient-matched device design from policy, clinical, and technological standpoints, and conclude the necessity of having clinical staff participation, a supportive role for medical engineers, and the potential for parametric modeling in design-manipulation software by the clinical staff. For parametric modeling, several advantages were found, as indicated below:

1) In a programmable modeling process, a set of necessary modeling commands can be included in an automatic order. This function can avoid clinical staff from memorizing mass modeling commands and lengthy sequences in learning the device design software to reduce the learning period and chance of failing to complete the sequence.

2) By customizing the interface, we can simplify the information volume in the operation to avoid clinical staff confusion or interruptions from unnecessary interfaces.
3) By incorporating embedded algorithms and logic judgements in the program, many parameters of controlling device features can be optimized or varied based on the anatomic model to improve the clinical staff's operative efficiency.
4) Programming such a semi-automatic modeling sequence requires less time and human resources than developing a commercial software.

These advantages can help the medical engineer develop the design manipulation software for the clinical practitioner and achieve the possibility of customizing the device independently by the clinical practitioner, rather than giving the prescription to the medical engineer. Therefore, a reasonable workflow should be like the map shown in Fig. 3.3, whereby the clinical practitioner and medical engineer can cooperatively work to develop a modeling process by a visual programing tool, allowing clinical practitioners to customize the PMD directly according the diagnosis.

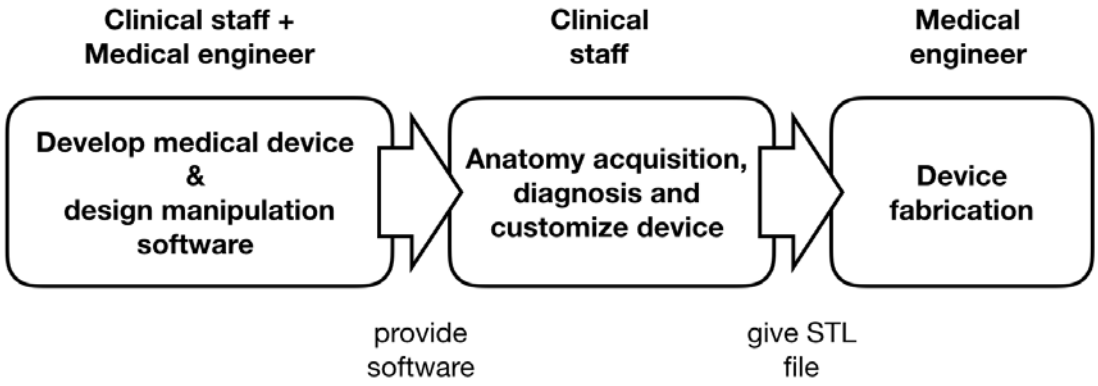


Fig. 3.3. Workflow of customizing device. The workflow integrates the techniques of clinical staff and medical engineer.

The modeling process can generate a perfect-fit model based on a patient's anatomical model and clinical staff's landmark range, using necessary features or structures to control the device's behavior or performance. Then, the determined device design can be output to the medical engineer for later fabrication. Through the collaboration, the clinician staff's experience and the techniques of medical engineers on hardware/ software solutions can be integrated.

Chapter 4
Collaborative Framework

4.1 Introduction

In this chapter, I submit a small-scale collaborative framework consisting of a medical engineer and clinician to develop a customizing tool for a specific medical device and explain their works at the early stage before development of the design tool, including defining the target device, the expected device functions and the unitary software environment.

Technically, digital fabrication realizes the personalization of a medical device; however, the customized device is unlike the standardized products in function and quality. The customization process of the device design is the key factor affecting the device's performance and precision to the treatment. In Chapter 3, I compared the properties of the medical engineer and clinical practitioner from the viewpoints of traditional customization and job duty, and I believe clinical practitioner is the ideal design agent in the customization of the device.

However, the digitalization of the device design stage causes significant technical isolation to clinicians. From the study of the direct modeling approach in the references and the comparison with parametric modeling, I submit a codesign concept executed by the clinical practitioner and medical engineer together to develop a specialized parametric modeling sequence for customizing a specific device to overcome the technical gap for the clinical practitioner [54,55]. Such a codesign development is a very rare experience to most hospital staff. Generally, the clinical practitioner does not have many opportunities to be involved in the early design stage of the medical product or software, and for the medical engineer, developing a variable product and customizing software is different from designing prefabricated products.

In this chapter, I introduce the overview of the collaborative framework and discuss the persona, necessary skillset and toolset of the two main roles [54,56]. The detailed method of the digital design tool is described in Chapter 5.

4.2 Framework Overview

4.2.1 Small-scale development

The framework map and workflow between the main roles are shown as Fig. 4.1. Main roles include multiple clinical practitioners and at least one medical engineer. For keeping the agility of tool development in the process, this method of development is suitable for small clinical teams inside the local hospital or division, rather than being applied in the R&D department of the medical manufacturer. Therefore, the medical engineer can clearly identify the clinician's design requirements by face-to-face communication to complete the tool development and training efficiently. Furthermore, in the latter applications, the medical engineer can make instant revisions according the issues that occurred in the training or diagnosis. Due to the complementary knowledge between the medical engineer and clinical practitioner, the development requires their high collaboration when following this method to develop their own device and design tool.

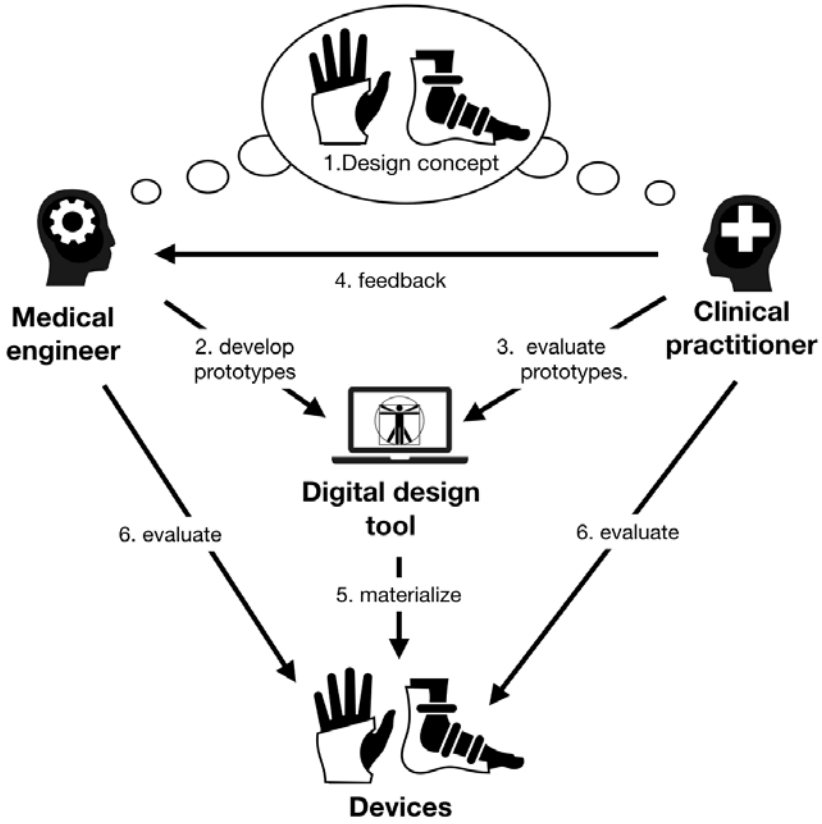


Fig.4.1. Framework map.

Unlike the development of mass production that intends to process extensive investigation to realize the overall issues on product utilization, the study collects

knowledge from a few clinicians who may present relatively narrow viewpoints, but the purpose of this stage is not to develop a uniform design tool for general clinicians. This study should reflect the collaborated result and viewpoint of the local group [32,57], and the generated design tool is a direct response to the local clinicians' concerns and requests. The decentralizing method encourages local groups to develop their own tools, devices and development culture and then to share these experiences and results on an open source and social platform with other groups [58]. The other groups can follow, extend or modify the shared design system for their own purposes.

4.2.2 Unitary software environment and specific device

The goal of this framework is to develop a modeling sequence for customizing a specific kind of device that can be completed in one CAD environment. Most cases learned in the references are supposed to be operated by a medical engineer, and the operative sequence usually requires multiple commercial CAD software as the sample in Fig. 4.2. These software are developed for various modeling requirements and provide different advantages in dealing with geometric objects, mesh models, or specific tasks, and in the workflow between CAD software, the device prototype is shaped gradually. However, the lengthy modeling sequence is a very time-consuming task, even for CAD experts.

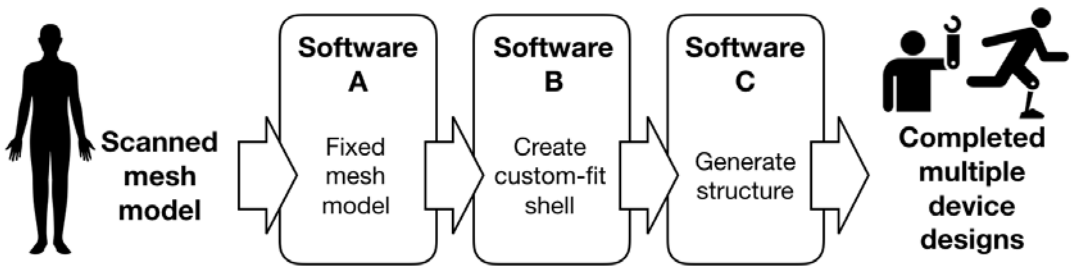


Fig. 4.2 Frequent workflow that requires multiple CAD software.

In the previous chapter, I argue that the above modeling sequence adopted in the references can be classified as a direct modeling approach, a free modeling method to explore the fuzzy model form by trying simple commands, but once a feasible modeling sequence of customizing device is confirmed, repeating the same sequence in every device design is not efficient. Therefore, I mentioned another modeling approach, parametric modeling, which is suitable for the latter situation by organizing a semiautomatic modeling process in the programmable modeling context based on the explored sequence from direct modeling (Fig. 4.3).

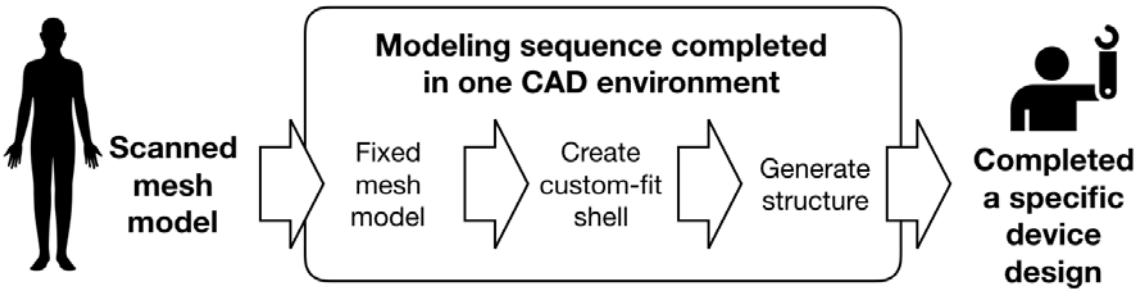


Fig. 4.3 Programmed modeling sequence in one CAD environment.

This modeling sequence should be limited to customizing a “specific” medical device, such as an upper-limb splint or a prosthetic, to limit excessive design extensions, rather than developing a multifunctional CAD software for various medical devices. Thus, the small-scale and agile development can save time from studying a huge user group and avoid the need to maintain bulky CAD software.

4.2.3 Design concept of device function

The purpose of the initial stage is to determine the basic features of the target device through the bilateral exchange of knowledge between the clinical practitioner and medical engineer. The frequent motivations of introducing digital fabrication technology into a medical device can overcome the disadvantages of a traditional device or provide better performance, such as comfort or weight, and clinicians and engineers should have the consensus on the goal of development. I list below directions that group members should investigate before developing the tool, via interview, probation or other communication iteratively.

- Study traditional devices: Clinicians are usually experts on making medical devices, and the medical engineer can study their cognition of device composition from practical probation or prototypes. Observing the traditional customization process is an efficient way to study how the traditional device is made by clinical practitioner in response to the treatment demands.
- Opportunity of digital fabrication: Clinicians may lack experience utilizing 3-D printers or handling 3-D printed objects, and medical engineer should introduce the possible opportunity provided by digital fabrication technology and customization approach. A demonstration of the objects made by digital fabrication and 3-D scanner to clinicians can help the discussion.
- Prototyping: Then, based on the study from the observation, the medical engineer can make simple and rough prototypes to simulate similar functions by manual modeling and the 3-D printer quickly for clinicians to compare with traditional devices and study the 3-D printed device’s performance on strength, weight, comfort and other

properties. Thus, clinicians can submit feedback to engineers for further prototype improvements [59]. The prototyping and feedback may need to be repeated a few times until the feasibility is confirmed.

- Limitation of clinician on operating the digital interface: Investigate daily experience and involved depth with the use of software or apps on mobile devices. Furthermore, a simple test of teaching viewport navigation and drawing task can be applied in the interview and evaluate whether they can follow.

After a period of iterative study, discussion and prototyping, the group should have a clear outline of the device's functions, advantages and customizing steps.

4.3 Skillset and toolset of main roles

As mentioned in the previous section, this development framework is not similar to the industrial company process for producing standard medical products for a commercial market and huge user group but is more similar to an internal development executed by hospital clinicians and medical engineers. Such highly integrated development is a rare experience for most medical engineers and clinical practitioner, and the required toolset and skillset are different from their original training and job. These conditions usually significantly affect how smoothly development progresses, so I address them in this section.

4.3.1 Medical engineer

Toolset

Medical engineering is a multidisciplinary category, and medical engineers may develop very diverse technical backgrounds for their practical needs. For clarification, qualified engineers can follow this method according to their tasks in the workflow, and I list several necessary capabilities as below:

1) CAD: In addition to having the ability to use CAD software to create geometric models, engineers should have wide digital geometric knowledge behind the commands and should be good at offering alternative solutions when a modeling approach fails for clinicians. Rich operative experience in product/mechanical design is preferred.

2) Anatomic modeling: Designing a modeling process to deal with various 3-D anatomic mesh models acquired from 3-D optical scanning or other medical imaging sources is a frequent task for a medical engineer in this position, and mesh modeling skills, such as smoothing the mesh surface or converting mesh into other type of geometric models, are useful.

3) Programmable modeling language: Programmable modeling language is a critical composing tool in this method because it is the main medium to connect mass modeling commands into a semiautomatic sequence. The medical engineer should be familiar with data structure and able to optimize the modeling sequence. Either visual programing language or text programing language is required, depending on the engineer's preference. Because the above tasks involve automating many software steps, engineers should know the FDA guide "General Principles of Software Validation".

Skillset

1) User interface design: The interface of the device design can be organized in the main CAD environment and programmable modeling tool's interfaces by the medical engineer, so the basic concepts and logic of the user interface design are required to simplify the information loading to avoid clinician's operative error.

2) Training formulation and user behavior evaluation: Because the above device design tool, design process and its interface are customized by the medical engineer, engineers needs to formulate an operative training content for clinicians. The training can include documents, videos, or one-on-one teaching. In addition, engineers should create a method to evaluate the clinician's learning, so engineers can identify what problem occurred in the clinician's operation, such as modeling program crash, unexpected model's generation or lost in the interface. The problem may be caused by an unstable modeling program, poor interface design or training, and the evaluation method should indicate the failure factor.

3) Experience in digital fabrication: As in the FDA guide, medical engineer will be in charge of the whole manufacturing process of the medical device, including the postprocessing and machine validation after the device design has been determined by clinicians. The medical engineer should be experienced in the 3-D printing data generation, hardware operation, and medical material with biocompatibility.

4.3.2 Clinical practitioner

Skillset

Unlike the diverse skills of the medical engineer, clinicians already have their own focused divisions and positions. Therefore, not many extra skillset requirements exist for them, and their original techniques and communication skills are important in the framework.

The traditional device customization technique and experience of the clinician staff are important sources for the medical engineer to study in terms of the clinical demands, device performance and operation logic. In addition, in the process, engineers may provide various prototypes of user interface or modeling sequence for their test and evaluation iteratively, so clinicians should be able to express clear user feedback in the operation or training for engineers to improve the prototypes.

Toolset

1) Customizing tool: One of the major challenges for clinician is learning the digital customizing tool for mastering the device design, and it is very different from the customization of traditional devices whereby formable material is applied to the patient's body directly. Most of the device design process is executed in the digital environment, thereby conferring many advantages, such as avoiding contact with the patient's body. This contact could cause pain in the fracture splinting. In addition, unlike the irreversibility of traditional material, plaster or thermoplastic sheet, the digital tool allows clinicians to test and evaluate different device designs and preview the results virtually. The tool is evolvable with the clinician's requirements and by the medical engineer's support. Unlike the long update cycle of commercial CAD software, clinicians can communicate directly with engineers, and engineers can fix the interface behavior or modeling sequence in response to feedback from clinicians in real time.

2) 3-D scanning: Compared to other medical imaging technologies, 3-D scanning is still the most economical option to acquire the anatomical data that some clinical practitioners, such as the occupational therapist or prosthetic technician, need to know when helping the patient achieve specific postures and execute the 3-D scanning.

Chapter 5
Digital Design Tool, Workflow and Training Formulation

5.1 Introduction

In this chapter, I present the detailed development of the workflow for building a modeling sequence, interface and input method for the device design determined in the previous stage (Fig. 5.1) and include the formulation of related training, design exercise and evaluation method. The digital design tool is a specialized tool developed for clinicians who do not have CAD experience to empower them, allowing them to engage in the customization service. In addition to learning about the tool, clinicians also need to take a quick training and design exercise to adopt the tool.

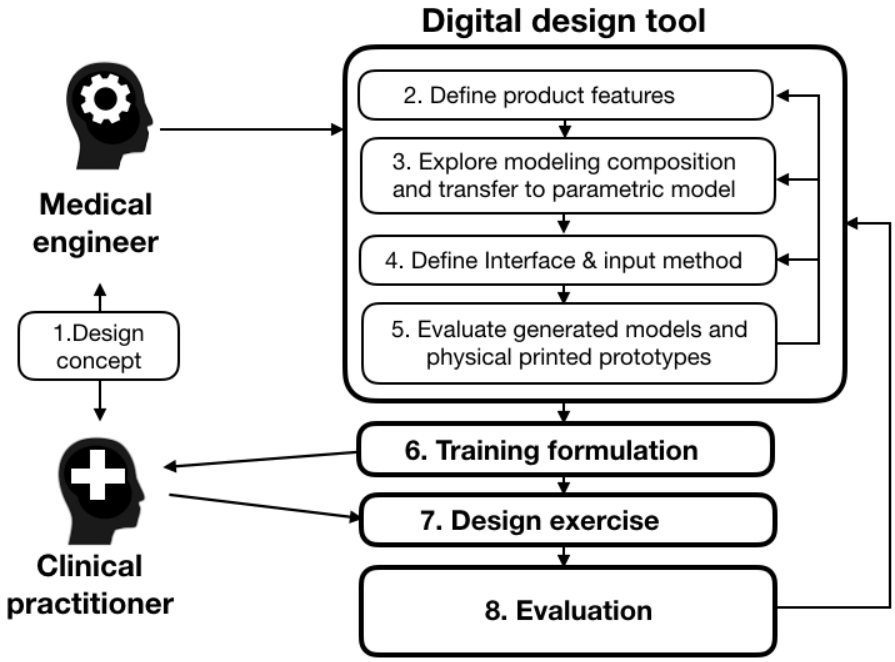


Fig. 5.1 Workflow of developing device design tool.

5.2 Digital design toolkit

5.2.1 Software environment and modeling strategy

Considering the requirement of programmable modeling, I utilized Rhino 3D Version 5 as the main modeling environment; this is recognized as a typical non-parametric CAD software. Hence, it has the flexibility of Direct Modeling, and can address the simultaneous existence of anatomic mesh and free-surfaces. Additionally, it allows the user to customize the interface and remove all unnecessary panels and tool bars. Moreover, its algorithm plug-in, Grasshopper 3D, is a widespread Visual Programming Language (VPL) among parametric modeling tools [51,52], and it is complementary to the flexible property of Rhino 3D. Besides, the software solution is not only limited by the pair of Rhino 5 and Grasshopper 3D, other CAD softwares plus their VPL plug-ins also works for the requirements of modeling environment, such as Blender, Fusion 360 and Dynamo plug-in. As addressed in Section 3.4, VPL is suitable for medical engineer who does not have text programing background, if medical engineer is capable of applying other scripting languages, more optional CAD softwares provide the application programming interface to archive similar modeling automation, such as Pro-E (Parametric Technology Corporation), SolidWork and CATIA (Dassault System). But In the steps described below, we utilized Rhino 3D to simulate the modeling sequence directly and transferred it to an automatic parametric model via the corresponding components (graphic icon showing the program command) in Grasshopper 3D.

Based on the feasible prototype studied in the design concept stage, the same prototype features can be achieved by several different approaches with diverse modeling orders or commands. Unlike the manual modeling of prototype development, the automatic modeling sequence when customizing a device can be repeated for uncountable times in every device design; it should be optimized to a stable tool. Frequent program crashes, generation of unexpected results, or overconsumption of time in modeling calculations will reduce the feasibility of this application; thus, medical engineers should carefully evaluate every modeling command and its order by comparing with other alternatives in the whole process. Several basic principles should be adopted by engineers in optimizing the device modeling sequence:

1) Avoid or reduce using the time-consuming components in the Grasshopper modeling calculation, such as all kind of Solid Boolean components (Fig. 5.2). The profiler widget in Grasshopper can help engineers to detect the time-consumed percentages of all components. Engineers can develop other sequences to replace the time-consuming component, if possible. Alternative sequences may include more components but are not necessarily more time-consuming.

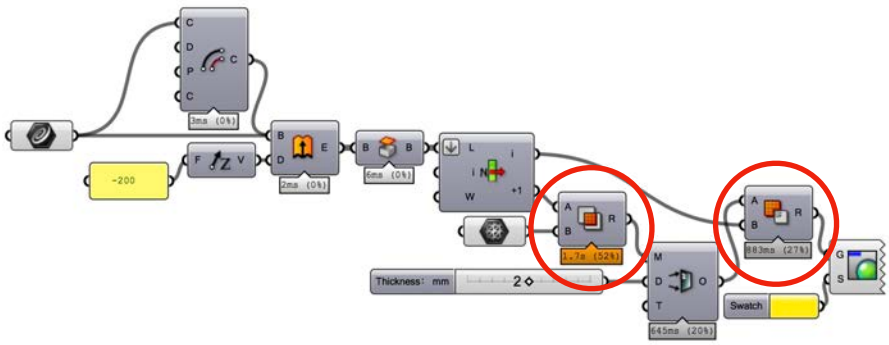


Fig. 5.2. Profiler widget in Grasshopper. It detects consumed time of modeling commands.

2) Study the optimal parameters: In the case of rebuilding the partial surface of an arm, creating multiple cross-section shapes on the arm is necessary for the Sweep command. Of course, 100 cross-sections can ensure high consistency compared to the reference arm, but approximately 20-30 cross-sections are good enough for a perfect-fit device (Fig. 5.3). Engineers should study the lowest requirements to reduce generation of unnecessary geometries.

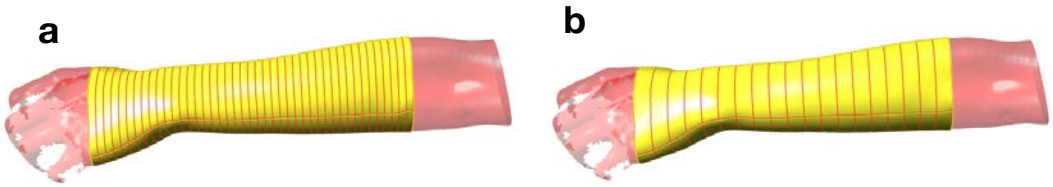


Fig. 5.3. Two surfaces based on different amounts of sections. **a**. The surfaces rebuilt from 45 cross-sections. **b**. The surface generated from 20 cross-sections.

3) Smart algorithm: Because the device size may vary with the anatomic model and treatment demand, related parameters should react with the change. The fixed thickness or structural parameters are impossible to be suitable for the devices with different sizes. Through CAE or FEM methods, engineers can find the optimal parametric range or coefficient to enhance the device strength.

In addition, the modeling method affects the device performance, and sometimes stable modeling does not equal better design. For example, five conceptual designs of 3-D printed wrist splints that are shown in the Fig. 5.4 are classified into two groups according to the modeling approach, and their two modeling approaches are “smooth exoskeleton” (Fig. 5.4.a) [61,62] and “engraved shell” (Fig. 5.4.b) [63-65]. In this comparison, the smooth exoskeleton has a faster modeling sequence, but the engraved shell can offer better comfort. Engineers should evaluate these options and compose the most stable sequence for the basis of later model programing and convert it into a semiautomatic modeling sequence by programmable modeling tool.

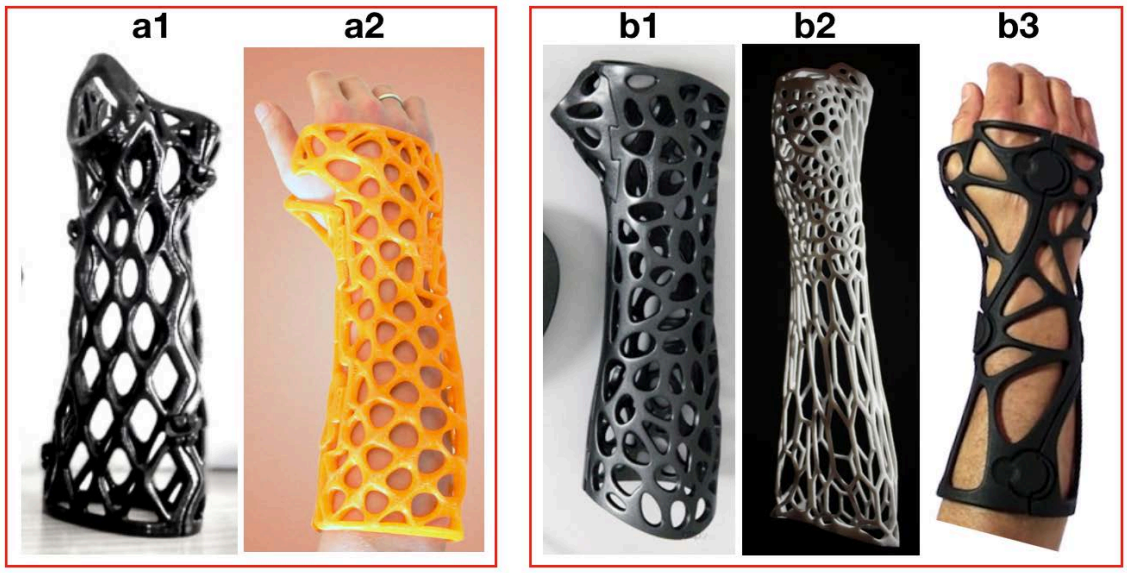


Fig. 5.4. Two different modeling approaches of splint design concepts. **a**. Smooth exoskeletons that developed from the poly line web, a1: A custom-made splint developed by ActivArmour company in United States (http://activarmor.com) [61]; a2: A 3-D printed cast developed by Russian company, Zdravprint, (http://zdravprint.ru) [62]. **b**. Engraved shells with the uniform thickness. b1: Osteoid Medical cast designed by Denis Karasahin in 2014,(http://www.osteoid.com) [65]. b2: Cortex, a 3-D printed splint designed by Jake Evill in 2013 [64]. b3: A 3-D printed splint developed by XKELET company (https://www.xkelet.com) [63].

5.2.2 Input methods

In the device design process, the input method should be designed based on the consideration of the limited CAD capability of clinicians. Several necessary input solutions are provided as below:

1) Select scanned mesh model and input to Grasshopper: Because most modeling works are executed in Grasshopper, the scanned mesh model is the fundamental input content for following steps. The scanned anatomical model can be input into a Mesh component in Grasshopper by the steps in Fig. 5.5a-c; thus, the program can obtain all properties of the anatomical model by adding other components after it, as shown in Fig. 5.5d, such as extracting its surface area or finding its center point, or even apply modeling steps to it. The mesh model can be scanned limbs, trunk, head or any part of the body.

2) Applying curves or points as landmark input: Beside inputting the scanned model, the modeling program needs landmark input from clinicians to decide the device features, and the point, poly-line, curve or closed shape are simple geometries can use for landmarking. In the example shown in Fig. 5.6, a closed shape that is joined by a poly-line and curve is input into Grasshopper, and the modeling program projects it on an arm model to generate a device shell.

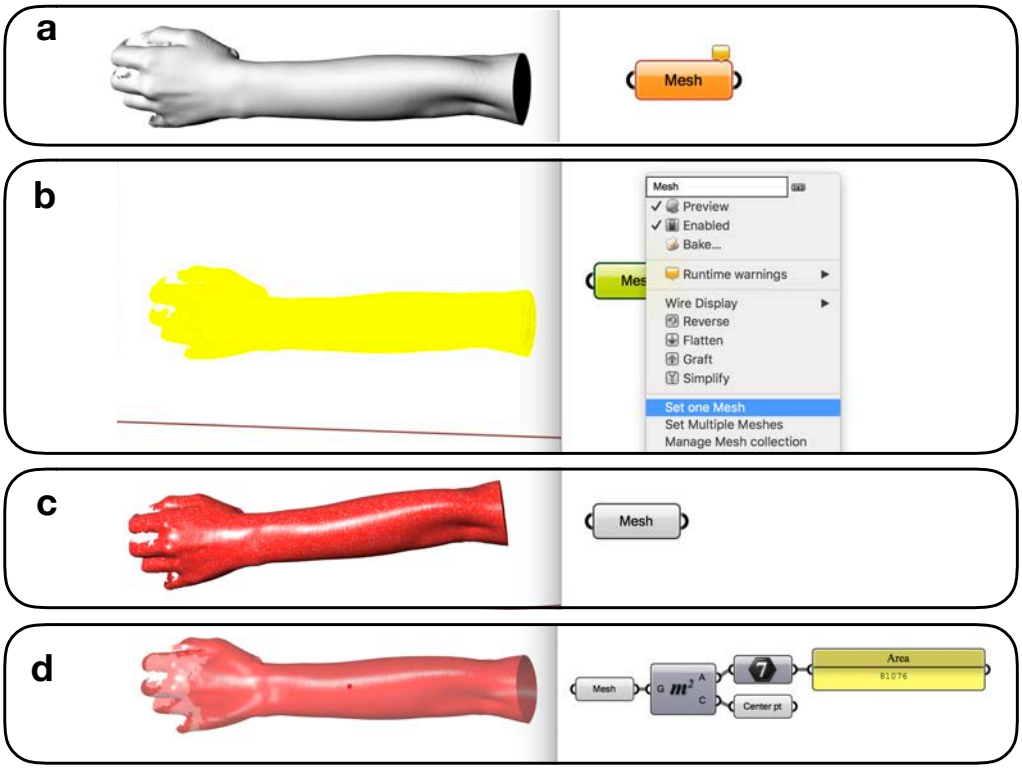


Fig.5.5. Setting scanned model into Grasshopper program. **a**. A arm model in Rhino and a Mesh component in Grasshoper. **b**. The arm model is selected and assigned into Mesh component by its component menu. **c**.The inputed arm model displayed in red implies it works in Grasshopper. **d**. The model can offer geometric information for other component's calculation.

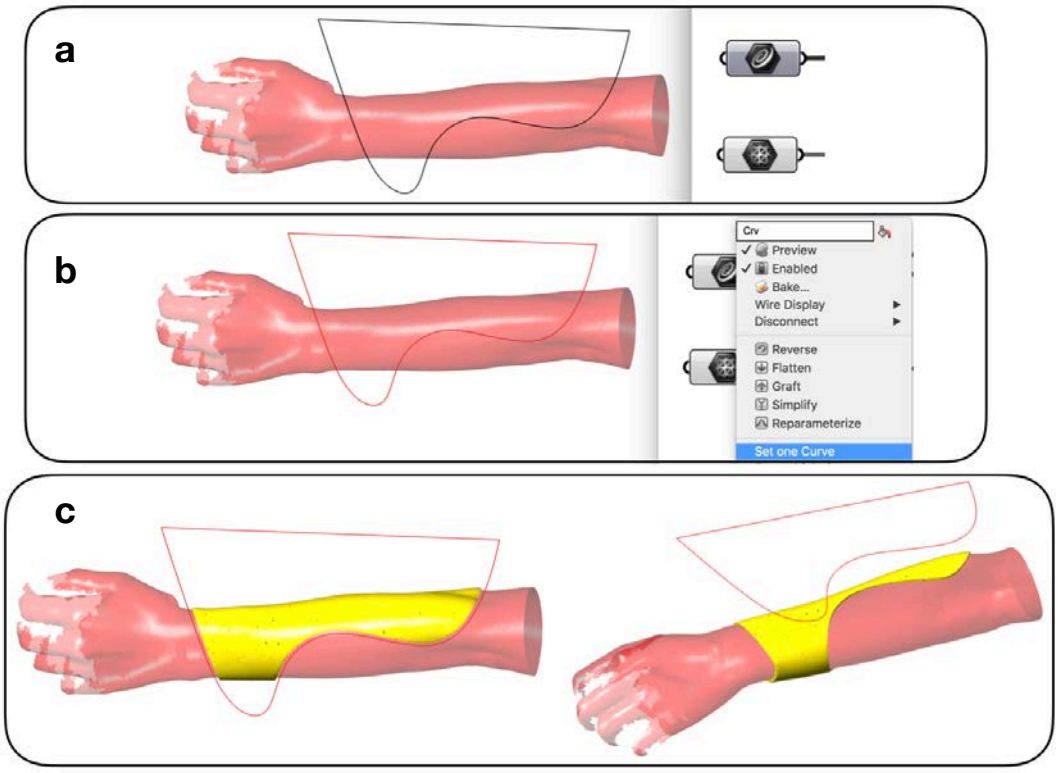


Fig. 5.6. Using curves for the landmark input. **a**. The closed shape is joined by poly-lines or curves . **b**. The shape is inputed into Grasshopper Curve component. **c**.Through the programed modeling sequence, the shape is used to generate a shell on targeted area of the arm.

3) Grasshopper component: In Grasshopper, various components can generate parameters, control the options or change the sequence in the modeling program. I list some useful components in Fig. 5.7. Slider Bar is the simplest component to output an amount to other modeling components, as it can give a variable to decide the shell thickness or screw amount for device assembly. Boolean Toggle is the frequent component that can output a True/False value to control the program that continues to the next step, such as exporting the final STL model file. Value List is an editable component to the output option code to decide the following subsequences

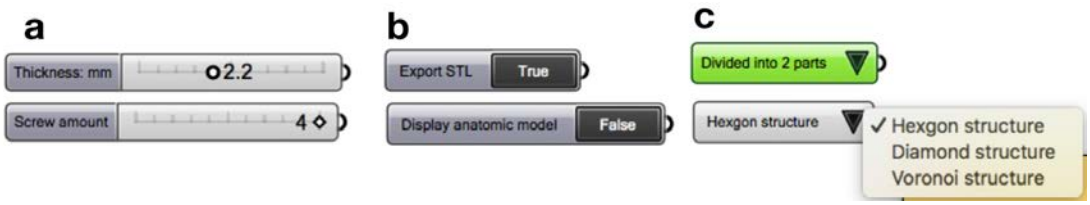


Fig. 5.7. Frequent components can input model data. **a**. Slider bar **b**. Boolean toggle. **c**.Value List,.

5.2.3 Design Principles of the interface

Once the modeling sequence is completed and optimized, engineers need to design a simplified interface and input method for clinicians because the program code is usually messy and complex (Fig. 5.8). Clinicians do not need to monitor the working state of the program operation; thus, medical engineers need to create a “skin” to encapsulate the program and help clinicians obtain the prototype state of the device model and transmit modeling control. Poor interface may affect the stability of the clinician’s operation of the design tool because of complex view windows and unnecessary information that will confuse clinicians. The issue also increases training difficulty and the rate of wrong operation.

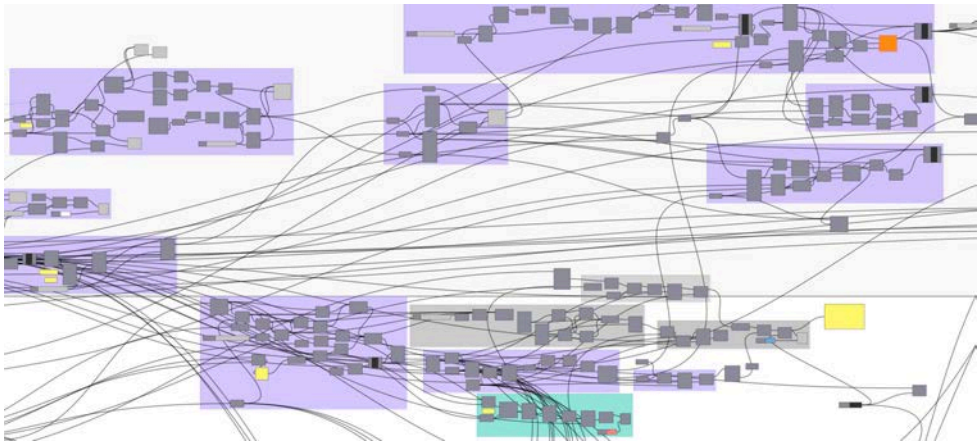


Fig. 5.8. Complex node-based program of Grasshopper 3D.

Although, many limitations exist when developing the design tool under an existing CAD environment, several strategies exist for customizing the interface for CAD-inexperienced users. Remove all unnecessary menus, toolbars and panels, as possible, and only retain the basic viewports for checking the device model state, such as the case in Rhino 3-D (Fig. 5.9).

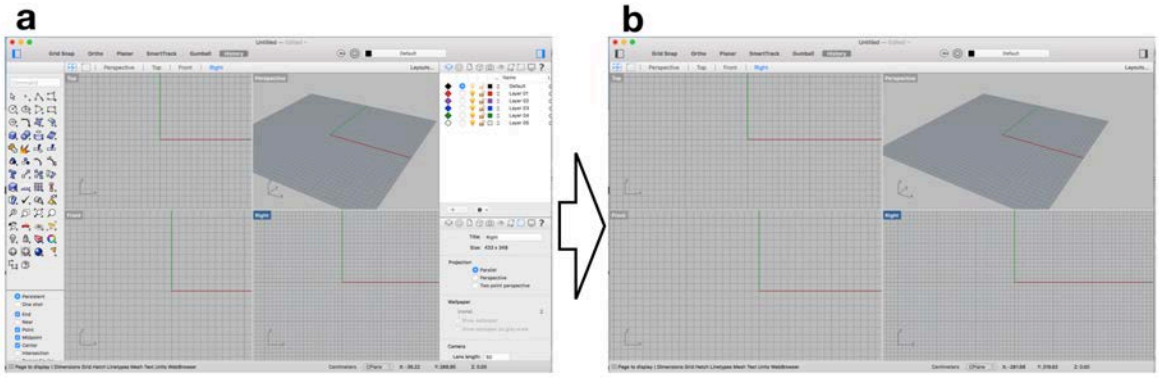


Fig. 5.9. Customized interface in Rhino. **a**. The original interface of Rhino 3D. **b**. Simplified interface. Most panels are removed.

Several interfaces can be edited according the modeling content; for example, the medical engineer can gather all control components and focus Grasshopper windows on them as an interface, as shown in Fig. 5.10a. The Remote-Control Panel of Grasshopper shown in Fig. 5.10b also has a similar function to gather slider bars, toggles, buttons or display information without accessing the components in the program, so Grasshopper windows can be closed in Rhino 3-D. In addition, the Human UI plug-in of Grasshopper can output the image of a specific viewport or visualized graphic from Rhino and gather slider bars on its own panel; thus, it can replace most interfaces.

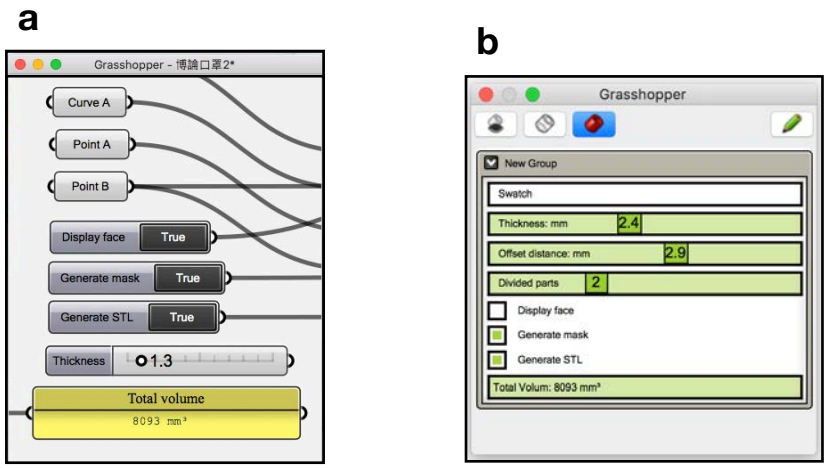


Fig. 5.10. a. Grasshopper interface **b**. Remote control panel.

5.3 Training, Design exercise and Evaluation

After the toolkit is completed, engineers should formulate a compact training content less than 30 minutes long for clinician to learn to use the customization system, and the training should include introduction, basic interface navigation, input method and trouble shooting. A design exercise on the use of the system should be arranged to simulate real design scenarios after the training.

5.3.1 Training formulation and design exercise

The introduction includes demonstrations of the digital models and physical device prototypes and explanations of the device design and 3D printing process to clinician. From the introduction, clinicians can learn how the device is assembled, produced and functioned for patient. Then, the computer-based tutorial should be provided by one-on-one teaching, and the necessary operational knowledge of the Rhino and Grasshopper programs is summarized as the following points:

- Basic viewport navigation in Rhino: The viewpoint operations include: zoom in/out, rotate view, pan move and switch viewport. These are basic skills necessary to identify the CAD space and evaluate the device models from any viewpoint freely.
- Set the curve or point for landmark input: The drawing curves or setting points are very simple input methods to trigger the later modeling procedure. Using Control Point Curve or Interpolate Points Curve are basic skills for the clinician.
- Select Rhino object and assign to Grasshopper: Selecting and setting objects are necessary steps to input the scanned model, curves or points into Grasshopper program. The clinician needs to learn the select, cancel selection, delete commands and identify the selected object state. After selecting the mesh model or curve, the clinician can input or clear setting contents in the input component menu in Grasshopper.
- Control data flow in Grasshopper: Clicking the toggles can change its output (True/ False) and then send out the geometric data to next modeling process. The device model will be updated by clicking toggles in order, and most toggles do not work if the previous toggle produced a false value.
- Solve program error or software crash: Sometimes, because the immobilization area overlapped on the anatomic model’s edge or a hole, the parametric model may generate a distorted surface, separate objects or have no response when attempting to update a model, even causing Rhino to crash. Correcting the immobilization area from the edge or hole can avoid these problems.

After the training, a design exercise should be designed to verify whether the clinician can perform the design capability. 5-10 different scanned samples are necessary for clinician to test modeling program stability and their reaction to different target models, and their design processes on the screens should be recorded as videos for further analysis.

5.3.2 Visualization of design agent behavior and analysis

In this section, an analysis method is introduced to visualize clinician's operation behavior and design performance from the recorded video of design exercises, and medical engineer can evaluate the design tool performance and training content from the visualized chart. In the interactive environment between Rhino and Grasshopper, the whole operation process can be recognized and classified as four statuses, include operation in Rhino, drawing geometries in Rhino, setting in Grasshopper and control in Grasshopper.

The design process is recorded from the screen as video, and the video should be monitored and marked with labels to identify clinician's operational movement (event) on the timeline as a bar chart (Fig. 5.11). This sample chart shows the video record of a

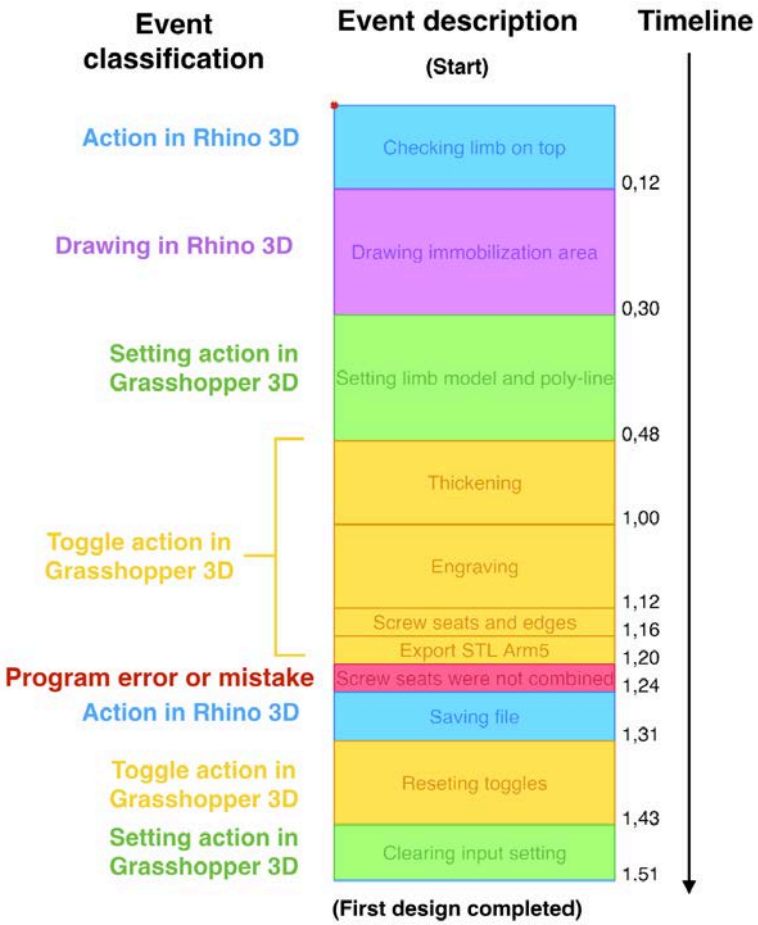


Fig. 5.11 A sample chart of visualized design behavior composed by color labels and timeline.

design process, a completed workflow that took 1 min and 51 s. We used 5 types of color labels to indicate the clinician's different purposes and working interfaces for each event on the timeline. The period of marking a label was initiated and completed according to the clinician's mouse clicks and the working interface. The purple label represents the drawing immobilization line, and we can determine how much time clinician spent on drawing to evaluate the difficulty of the task. The yellow label represents the waiting time after the clinician clicked the toggles to obtain an updated model, and this was equivalent to the overall time of the modeling calculation. Program errors of the parametric model or operation faults are indicated by the red label, and the length of the red label represents the required time that clinician needs to solve the situation and continue with the correct workflow. These labels can visualize where and how the errors and mistakes occurred and the time expended on each event. Thus, we could improve the parametric model or training program.

After the clinician completed the exercise, an interview should be held. If the clinician's intention for any event was not obvious enough to determine a label, e.g., they were confused or forgot a step, the medical engineer should confirm what occurred with the clinician in the interview. However, the main purpose of the interview was to collect the clinician' opinions regarding the design tool and training program based on their experience.

5.4 Quality check

According to the Device Testing Consideration in the U.S. FDA guide [40] and the main device types that appeared in the reference study, the necessary evaluations for the product includes the mechanical test, comfort investigation, cleaning and sterilization, which should be performed in the development of the modeling sequence or when physical prototypes are available.

5.4.1 Mechanical test

For the splint, ankle-foot orthoses, and prosthesis, devices that may take the internal impact from the patient's body when moving or from accidental forces when the patient hits another object, a mechanical test is required to ensure the devices have enough engineered strength. The testing methods may include applying Computer-Aid Evaluation (CAE) software or a physical testing machine. In the early stage of developing the design tool, finite element analysis is a frequent CAE method used to predict the mechanical response of a device component under the defined loading conditions; it is available or integrated in some CAD software, such as ANSYS (ANSYS), Solidworks (Dassault Systèmes Solidworks Corporation) or Fusion 360 (Autodesk), (Fig. 5.12)[29,32,66,67]. Because, in the modeling program, the device

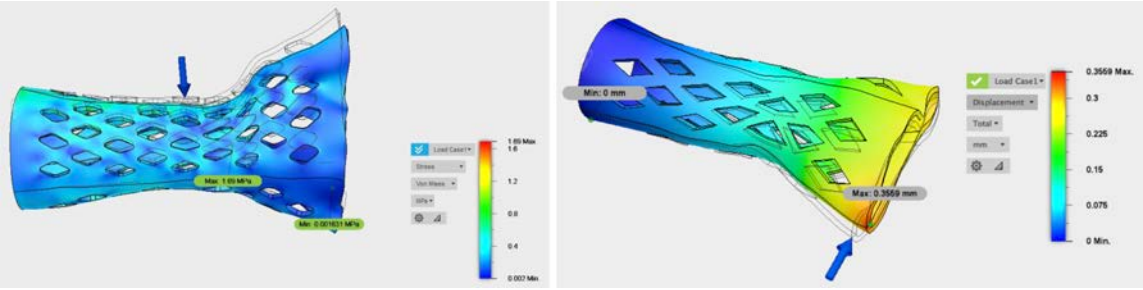


Fig. 5.12 A FEA result of splint calculated in Fusion 360 (Autodesk). **a**. The maximal stress. **b**. maximal deformation.

thickness or structural parameters can vary along the whole device size and form, the medical engineer should calculate a conservative coefficient range for thickness or structural input from testing mass generated models by FEA iteratively to ensure the generated devices are equipped with enough strength. After the modeling program is completed, engineers can pick a few worse-case printed products to test their stiffness or stress with measuring machines, as shown in Fig. 5.13 to verify FEA result.

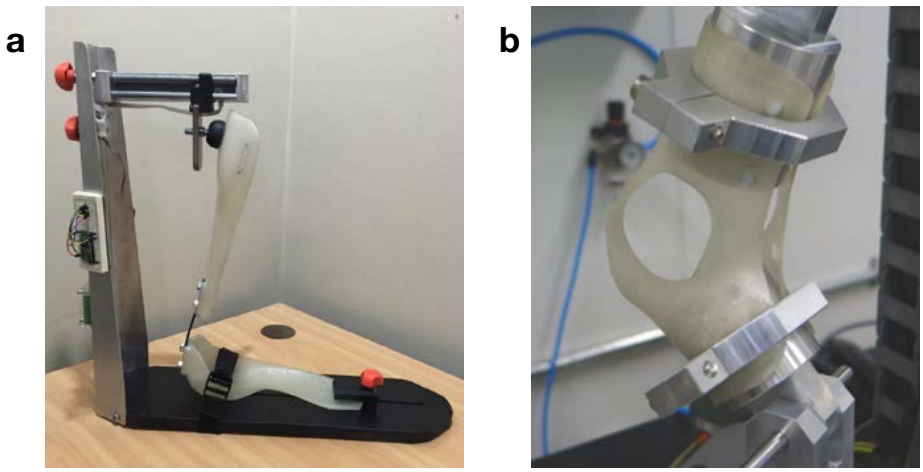


Fig. 5.13 Measure machines. **a**. A custom machine developed by Mark Walban, Turner K and Andrew McDaid in page 8 of their article “Customized 3D printed ankle-foot orthosis with adaptable carbon fibre composite spring joint.” for the stiffness testing [33] **b**. Mechanical stress testing is applied by Yong Ho Cha, Keun Ho Lee, Hong Jong Ryu, Il Won Joo, Anna Seo, Don-Hyeon Kim and Sang Jun Kim in their paper of “Ankle-Foot Orthosis Made by 3D Printing Technique”, page 4 for evaluating the durability of the 3D-printed AFO. [31]

5.4.2 Biocompatibility, cleaning and sterilization

As the FDA’s guidance’s recommendation the biocompatibility of final finished device should be evaluated as described in the guidance “Use of International Standard ISO-10993.” The evaluation should consider whether the patient’s skin is exposed in the long-term contact with the devices in the cases of splint or prosthesis; whether the medical grade materials match the ISO-10993 standard recommended in the device manufacturing to ensure the material safety [23,40,68], such as MED610TM (Object), ABS-M30i (Stratasys) or Fabrial-R (JSR) filament (Fig. 5.14); and whether the material

is watertight enough to isolate the internal voids of device and avoid the external pollutions remaining and accumulating.

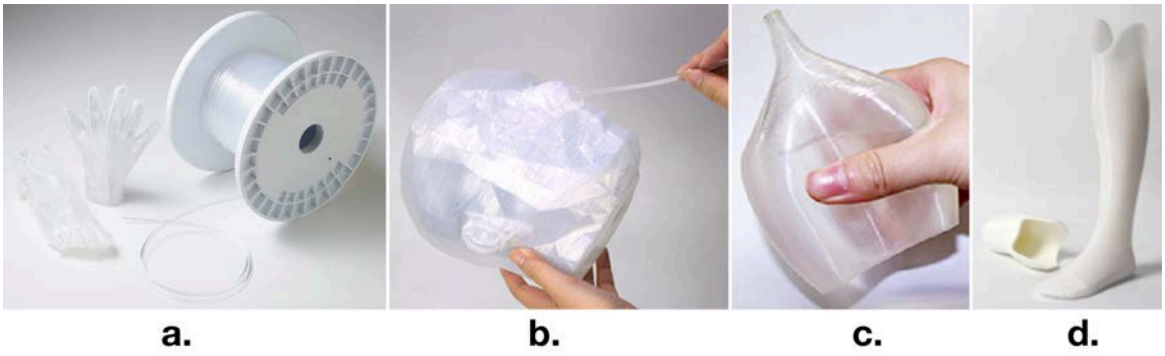


Fig.5.14 Medical-grade filament and medical studies. **a**. Fabrial-R filament of JSR company, (http://www.jsr.co.jp/news/0000613.shtml). **b**. Head model for nasogastric tube feeding training designed by Miyagawa Shoko Lab of Keio University, 2017. **c**. Prototype in the study of Fabrial-R's softness and watertightness, by Kiba Shintaro at Hiroya Tanaka Lab, Keio University, 2015. **d**. Prosthesis prototype made by the same material by Masuda Tsuneo, SHC Design company.

Due to the unique interlayer bonding of 3-D printed parts in the z-direction, a mass of tiny grains is among the layers on the surface, and these grains are expected to increase the difficulty of cleaning and sterilization, due to the likelihood of increased surface area and generation of extensive tortuous pathways. Most devices have application for patient's daily usage, and to maintain the device's basic cleanliness, daily sterilization is necessary. Engineers should verify the result and that the frequent sterilizing method works on the devices by collecting bacteria on an the agar medium from the surface of sterilized device and keeping the medium in an incubator set at 37 °Celsius for 48 hours to detect the total viable bacterial count (Fig. 5.15).

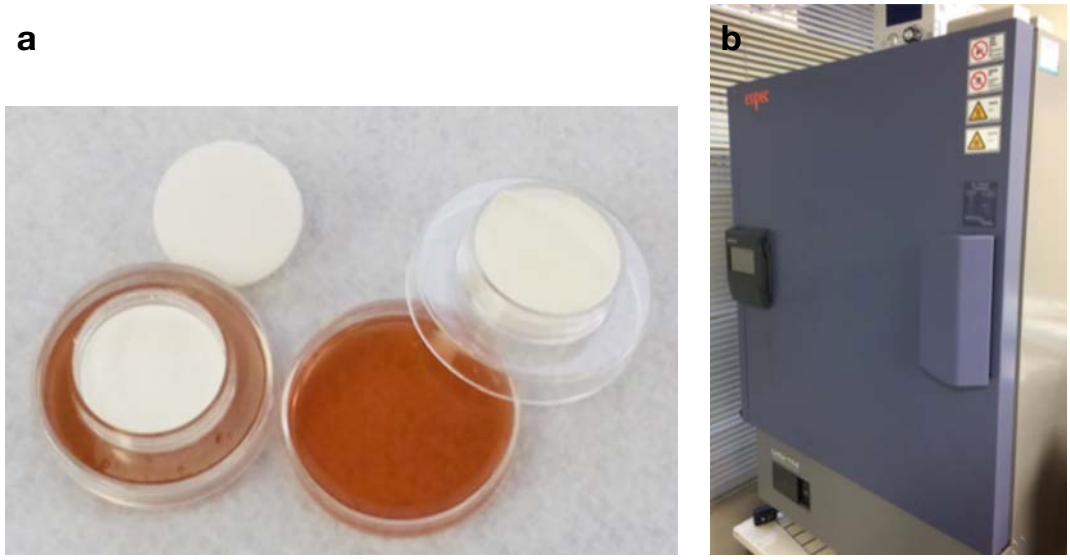


Fig. 5.15 Bacteria growing test **a**. Agar medium with a cotton collector for the sample surface difficult to reach, Sun Chemical CO., LTD. **b**. Incubator for bacteria growing.

5.4.3 Comfort investigation

Although every medical device will not need the same level of anatomical matching or imaging accuracy for optimal device performance, some factors from hardware or software conversion may affect the precision of the device fit. In addition, soft tissues and nonrigid structures may cause deformation at the target location when compared to the reference image. Loose fitting or inconsistent geometric shapes are difficult to identify and will cause pressure points at different levels during wear [14,69,70,]. Therefore, engineers should invite health volunteers to try their prototypes to detect the possible range on fit level afterward by interview or questionnaire.

Chapter 6
Experiment

6.1 Introduction

To evaluate the actor framework and digital design tool, I conducted two experiments on two wearable devices and constructed their collaborative frameworks and evaluation methods, as shown in Table 6.1. The two devices were originally handmade with raw material or mass produced, and through 3-D scanning, modeling and digital fabrication, the products were customized in the experiments.

Table. 6.1. Summary of framework, result content and evaluation events in two experiments.

<table>
<tr><th></th><th>Product</th><th>Design agent</th><th>User</th><th>Result (System)
Chapter 7</th><th>Evaluation (Training)
Chapter 8</th><th>Evaluation (Product)
Chapter 8</th></tr>
<tr><td>Exp. 1</td><td>Fracture splint</td><td>Orthopedist Therapist</td><td>Fracture patient</td><td rowspan="2">• Efficiency of generating models
• Prototype fabrication</td><td rowspan="2">• Training
• Design exercise</td><td>• Finite Element Analysis
• Wearability evaluation</td></tr>
<tr><td>Exp. 2</td><td>Filtering respirator</td><td>Infection Control Practitioner (ICP)</td><td>Health care worker</td><td>• Qualitative Fit test
• Comfortability
• Sterilization
• Bacteria verification</td></tr>
</table>

Two digital design toolkits, namely, the customization system developed from the pre-study with design agents, based on the original experience of users, products and evaluation methods. The design agents in these experiments have knowledge about how the products work and are evaluated, but they have no experience or skills about these digital technologies. Therefore, the interface, input method of system and training content for design agent were formulated with consideration for their limited CAD capability and customization experience.

In the two experiments, the product prototypes, customization system, and training of design agents were evaluated and addressed in Chapter 7 and 8. Two sets of design agents were invited to attend the design exercise and execute the customization design for provided scan samples. From the generated printable models and required time of design exercises, we were able to evaluate the system for its success rate and efficiency and to evaluate the suitability and information content of the training. From the fabricated prototypes, we can evaluate the product from the mechanism test and user feedback on wearability and comfort.

6.2 Experiment 1: upper-limb fracture splint

6.2.1 Introduction

Framework

In this experiment, I selected upper-limb splints as the customizable product, and the user is a fracture patient. The design agent is clinicians because casting splints to immobilize a patient's injured limb is part of fracture treatment. The framework and interaction between actors are visualized in Fig. 6.1.

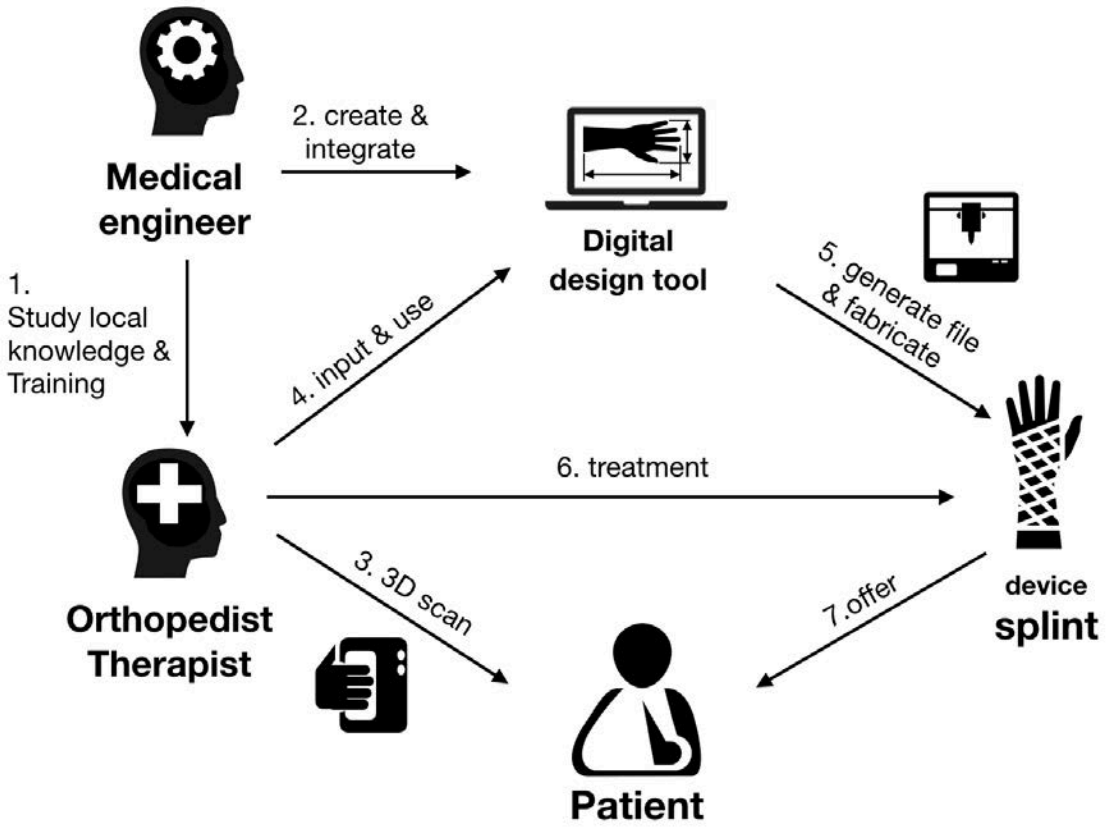


Fig.6.1. Framework of Experiment 1.

Motivation

Upper-limb splints are employed for immobilizing fractures, congenital deformities, and for chronically degenerating orthopedic conditions. Plaster and thermoplastic sheets are the primary materials used in conventional fracture immobilization. In the splinting process, owing to the irreversibility of these materials and the body-based contacting model, the splint-fitting effect depends on the experience and skill of the clinician; the patient's treatment experience varies significantly, depending on the clinician [29,69,71]. In addition, conventional splints are bulky and unsightly, causing obvious inconvenience to patients, during treatment. As keeping the splints clean and dry is difficult, the risk of infection increases [29,72].

In recent years, the introduction of 3D printing for orthopedics and rehabilitation practice has been extensively discussed because 3D printing technology renders it possible to customize splints and increase patient treatment satisfaction [16,29,70,72]. The concepts of 3D printed splints which have appeared recently in the media, are lightweight, well-ventilated, waterproof, and aesthetically pleasing, addressing nearly all the deficiencies of conventional splints [27,63,70,72,73]. Moreover, non-contact scanners can replace physical casting to acquire the anatomic surfaces necessary for the fabrication of splints, and prevents patient discomfort and induces less distortion of the target region [9,74].

Challenge

3-D printed splints have mainly benefited from three digital techniques. The three digitized processes involved in splint printing include [9,25,75].

(1) acquiring splint mesh model from the patient's affected limb surface by means of a 3D scanner.
(2) designing the splint model using computer-aided design (CAD) software tools and exporting fabrication data.
(3) fabricating a physical splint by using of a 3D printing device.

Nonetheless, several issues exist in the above mentioned digitization processes. The quality and accuracy of the scan of the patient's affected limb plays a critical role in determining the success rate of the split model subsequently designed. Occurrence of irregular holes in the scan are a common sight on the dark side of the limb model and skin wrinkles are observed between fingers where the scanning light rays cannot reach [30]. In addition, it is difficult for an injured person to maintain the required posture the during 3D-scanning exercise, and even slight uncontrollable shaking of the patient's limb can result in partial deformations or distortions appearing in the final scan. When employing the deformable alignment technique [30,76,77], acquiring a complete result

during the scanning process requires use of additional software, relevant techniques, and post-processing; this invariably involves increased investment of time and cost as well as specialized training to be provided to clinicians.

Besides, in the 3D modeling stage, the design task of this stage is not only to generate a patient-specific shell according to the surface of the affected limb but also to control the density and thickness of the ventilated structure based on the surface. The structure and its volume impact the orthosis strength and printing time. Additionally, the necessary wearable designs, such as flexible gaps, hinges or interlocking components, are generated at this stage as well. It is often a difficulty for the clinician to achieve initial treatment, design, and modeling steps in a 3D virtual environment, and this challenge includes the required time for orthosis modeling and the significant learning period necessary to utilize the specific CAD tool.

Objective

In this experiment, I develop a precompiled customization system to aid the clinician in designing 3D printed splints using the programmable modeling tool. The complex modeling sequence of splint design is integrated into a semiautomatic system and the clinician does not need to repeat lengthy modeling operations; further, the operations are not limited by the CAD skill level of the operator. In addition, the parametric environment enables the automatic calculation of the thicknesses and lattice patterns of various splints and divides the splints into multiple components for efficient printing.

6.2.2 Method

This section presents operational guidelines to simply tasks involved at the 3D-scanning stage. Detailed steps and procedures followed in the development of the proposed semiautomatic system for splint design through use of a programmable modeling tool, to address problems encountered during other stages, have also been discussed.

Flaw-tolerant Scanning

Following strategies were applied to address difficulties encountered during the scanning stage, at present.

(1) Holes existing in the model may be repairable during the modeling process; however, it is difficult to restore deformations and distortions, caused by shaking, to their correct form. In this respect, flaw-tolerant scanning is highly beneficial in completing a scan more quickly, hence reducing the possibility of errors induced owing to uncontrollable shaking.

(2) Additional post-production procedures after scanning must be avoided, and only simple clipping must be performed to remove unnecessary environmental background and/or body regions.

A handheld scanner, Sense (3D Systems), was used in this study for scanning and subsequently generating an output mesh model of a limb. The said scanner is affordable and lightweight, and its software offers only basic functions, such as background clipping. Five scanned samples were obtained from healthy adult volunteers (as depicted in Fig. 6.2(a)) whilst following above-mentioned principles. The scanned samples were used to simulate different immobilization ranges in the result, and completely scanned regions included fingers along with the palm, wrist, and fore arm. The time spent in successfully scanning these regions was in the range of 40–60 s. When performing the scanning operation, the operator must ensure plenty of elbowroom and light availability around patients' limb. Correct use of a handheld scanner and its smooth motions along the scan path are key factors that influence efficient completion of the scanning operation. No built-in light source was available within the scanner used in this study; few holes were observed to have been unintentionally created on backlight surfaces of Samples A and E (Fig.6-2(b)). Although occurrence of deformations in the finger area is obvious, the palm and forearm regions remained unimpacted.

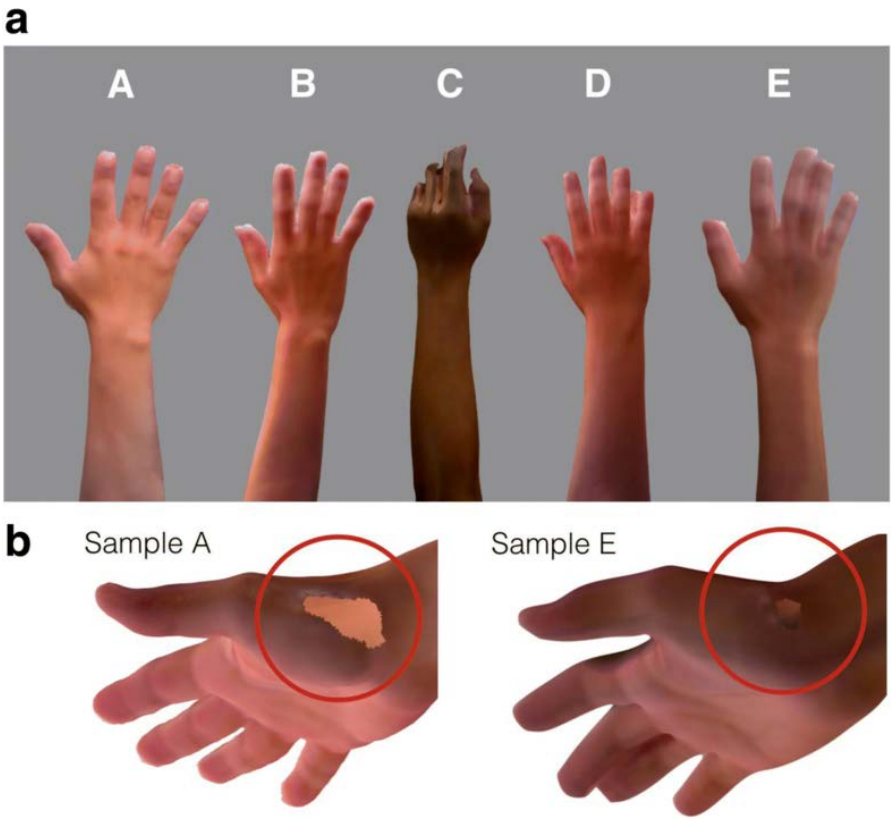


Fig. 6.2. Limb samples from five volunteers. **a**. Limb samples; **b**. Sample A and E and associated flaws.

The said samples were used in the subsequent modeling process. For reducing the scanning time and deformation, the authors recommend use of a DIY device (Fig. 6.3).The scanner mount was made by aluminum rail sticks and the scanner was installed on its rotor arm. A support table was placed under the mount's axis, and the patient's upper arm for the affected limb was supported to align with the axis. The scanner on the rotor arm could be rotated and moved along a circular path around the limb smoothly by rotating the crank handle and was maintained at a stable distance from the limb. The device can effectively reduce the total scan time to 20–30 seconds.

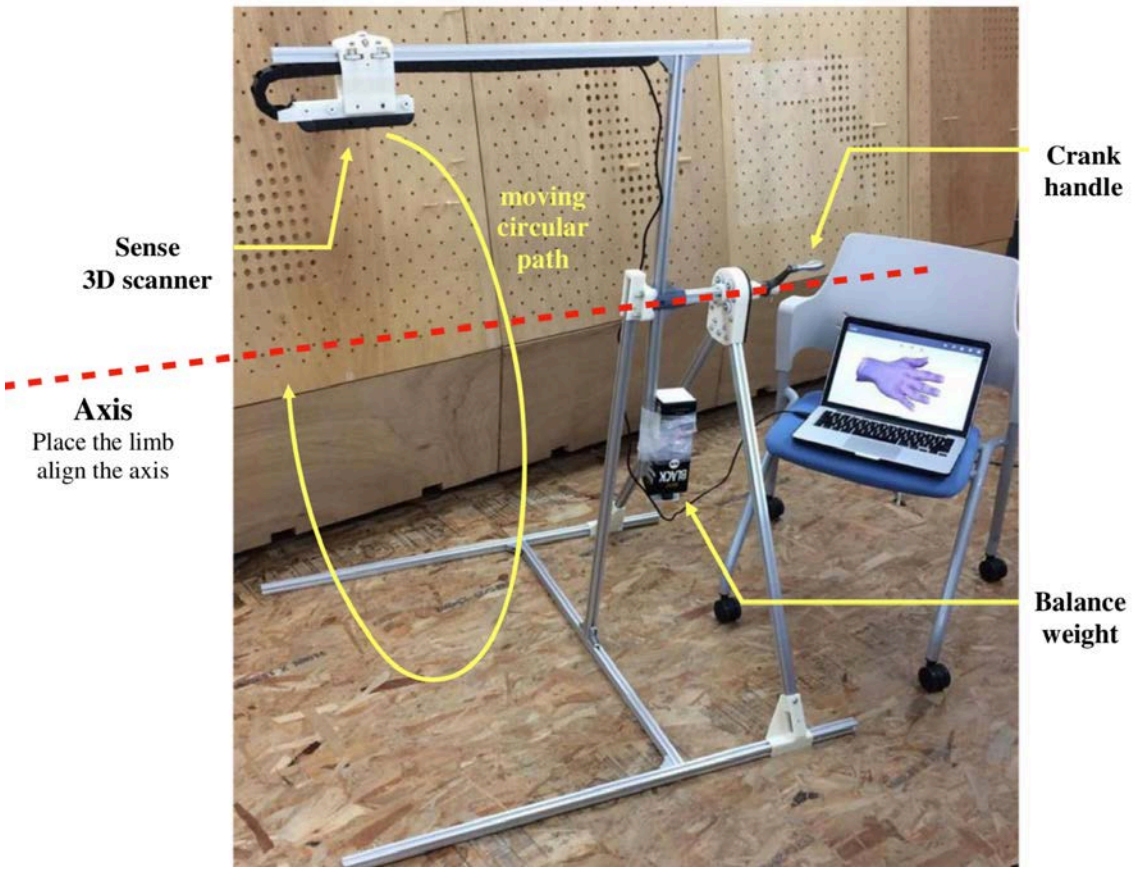


Fig. 6.3. 3D scanner mount.

CAD environment

The proposed study is not aimed at generating a tedious manual model to be employed by the clinician during treatment. The modeling task has been compartmentalized to be implemented via two roles—the medical engineer and clinician. A medical engineer familiar with the use of CAD software and programming languages can follow the detailed methodology below to create a semiautomated customization system in advance. A clinician is the end user of the precompiled design tool, and plays the role of the design agent—to execute splint design in accordance with patients' conditions. The clinician does not need to know how the program works, and can, therefore, instead focus on the design and evaluation of splint models.

Software options for digital splint designs have been listed and comparisons between self-developed and existing CAD software have been performed in [78, 79]. Considering programmability requirements for designing such a system, Rhinoceros 3D Version 5.0 (Robert McNeel & Associates) was used as the primary modeling environment jointly operated along with a visual programming tool—Grasshopper 3D (Robert McNeel & Associates).

Definition of splint feature

Splint designs generated using the proposed system exhibit features depicted in Fig. 6.4. Corresponding standards are as described below.

- Division: The proposed system divides the splint into a 2- or 3-part set depending on the splint size. If 2 or 3 3D printers are available for concurrent use, the splint fabrication time could be reduced to 1/2 or 1/3 the original build time, respectively.
- Lattice structure: Splint lattice patterns are created by means of a diamond structure to reduce weight and support material during printing as well as increase ventilation [77].
- Assembly method: Screw seats are generated along long edges of each divided splint part to facilitate assembly by means of plastic M3L10 flat-point Phillips screw sets with prefabricated screw caps (Fig. 6.4(b)). The number of screw seats used depends on the edge length.
- Rounded edges: Splint edges are designed to be of tubular shapes to prevent skin abrasion due to sharp/rough edges [29, 70].

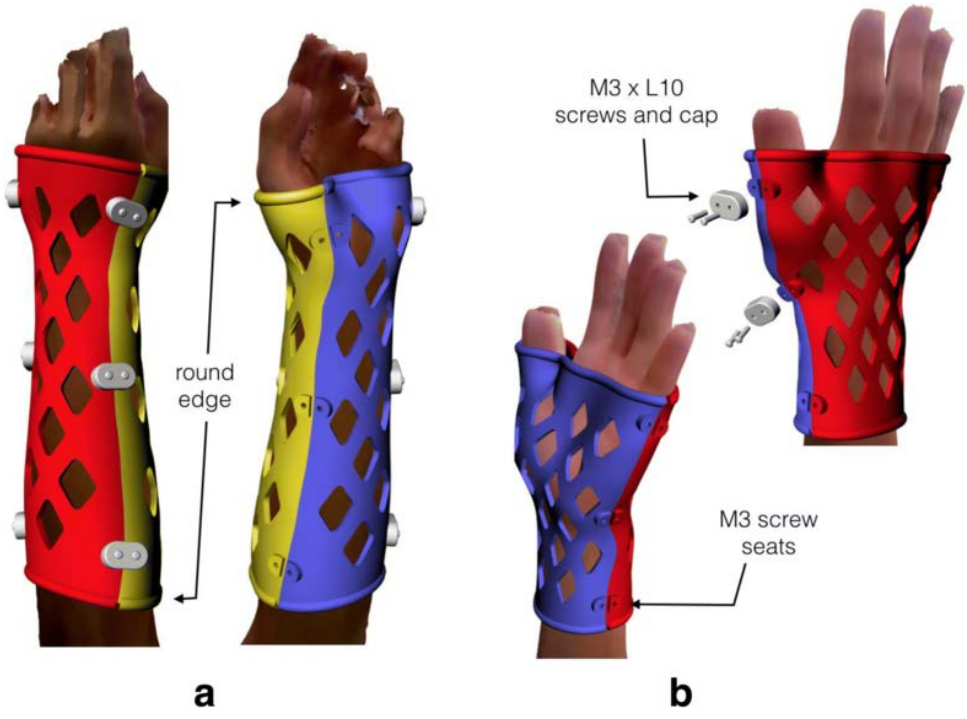


Fig. 6.4. Defined splint features. **a.** 3-part set, **b.** 2-part set for wrist splint.

Modeling workflow and program overview

In view of the above features, several different modeling sequences were tested via manual operation for building the same splint in Rhinoceros 3D, and a modeling workflow was determined after repeated comparisons, as depicted in Fig. 6.5(A). The modeling system was divided into five stages and switched over to Grasshopper 3D—a node-based program (Fig. 6.5(B)). The program comprised various components (marked by tiny gray and yellow tags) with each component performing an exclusive function, such as creating geometries, performing calculations, and making logical judgments. Individual components are connected by wires passing from left to right, thereby expressing input–output relationships. As the program is too large to be included in this manuscript, a simplified program for each stage has been described. In accordance with the workflow, program blocks in Fig. 6.5(B) have been marked as input model and curves (Fig. 6.5(b1)), basic covering-surface generation (Fig. 6.5(b2)), division and thickness generation (Fig. 6.5(b3)), lattice-structure creation (Fig. 6.5(b4)), and rounded-edge and screw-seat generation (Fig. 6.5(b5)).

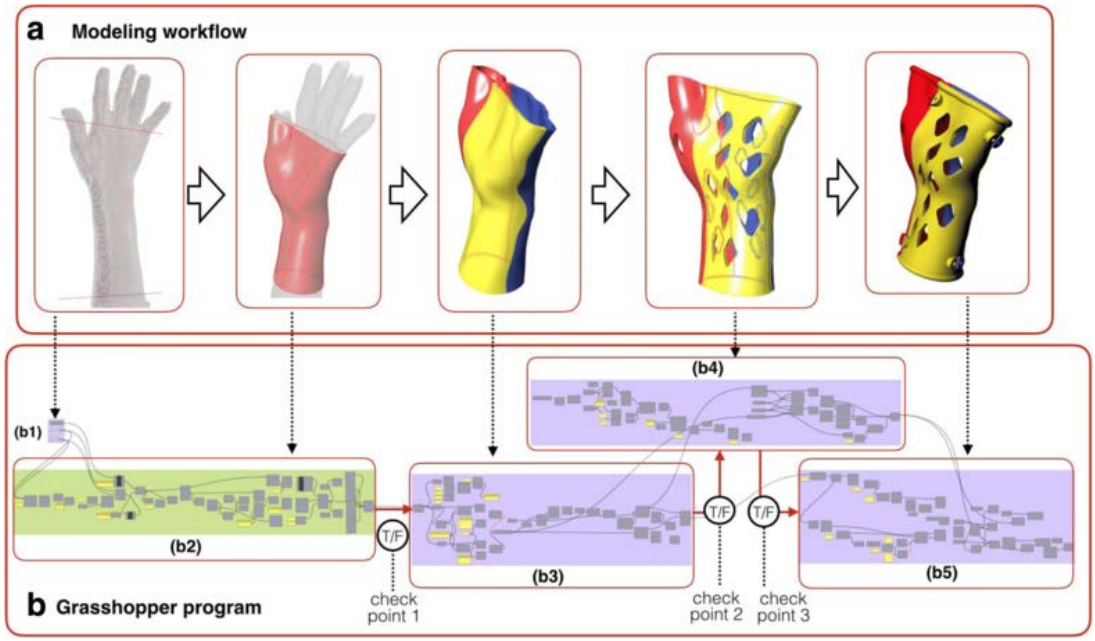


Fig. 6.5. Program workflow and overview of five stages and check points. **a**. Modeling workflow; **b**. Grasshopper program—(b1) Input model and curves, (b2) Basic covering-surface generation, (b3) Division and thickness generation, (b4) lattice-structure creation, and (b5) Rounded-edge and screw-seat generation.

All above stages are not executed in a single continuous process. Data flow during each stage is controlled by the three checkpoints depicted in Fig. 6.5(B). At each checkpoint, clinicians examine the splint status and confer a true value before continuing onto the next step or modifying the input area. Therefore, splint models is not generated instantaneously when the input is fulfilled; it gradually takes shape as the modeling procedure progresses. If the entire splint model were to be constructed using a single automated process, the concerned computation would be completed within tens of

seconds. In that case, however, the modeling process may fail to generate a valid result if unforeseen problems are detected during modeling or computations involved in one of the stages. Furthermore, in the event of such a case, clinicians would not be able to identify the step that caused the system to fail. By using checkpoints, however, clinicians can decide to modify input curves, pattern-density parameters, and/or position of screw seats depending on the stage at which the failure occurred. Various reasons that potentially contribute to failure and corresponding appropriate responses are described in the next section. An advantage of the five-stage strategy is that it consumes a very little time to perform required computations at each stage, and the stage at which problems occur can be easily identified.

Limb-model import and immobilization-area assignment

After import into Rhinoceros 3D, the scanned limb model must be manually placed along X-axis of the software coordinate system with the palm facing up/down, as depicted in Fig. 6.6(a). The clinician subsequently selects the model and assigns it to the mesh-input component in Grasshopper 3D.

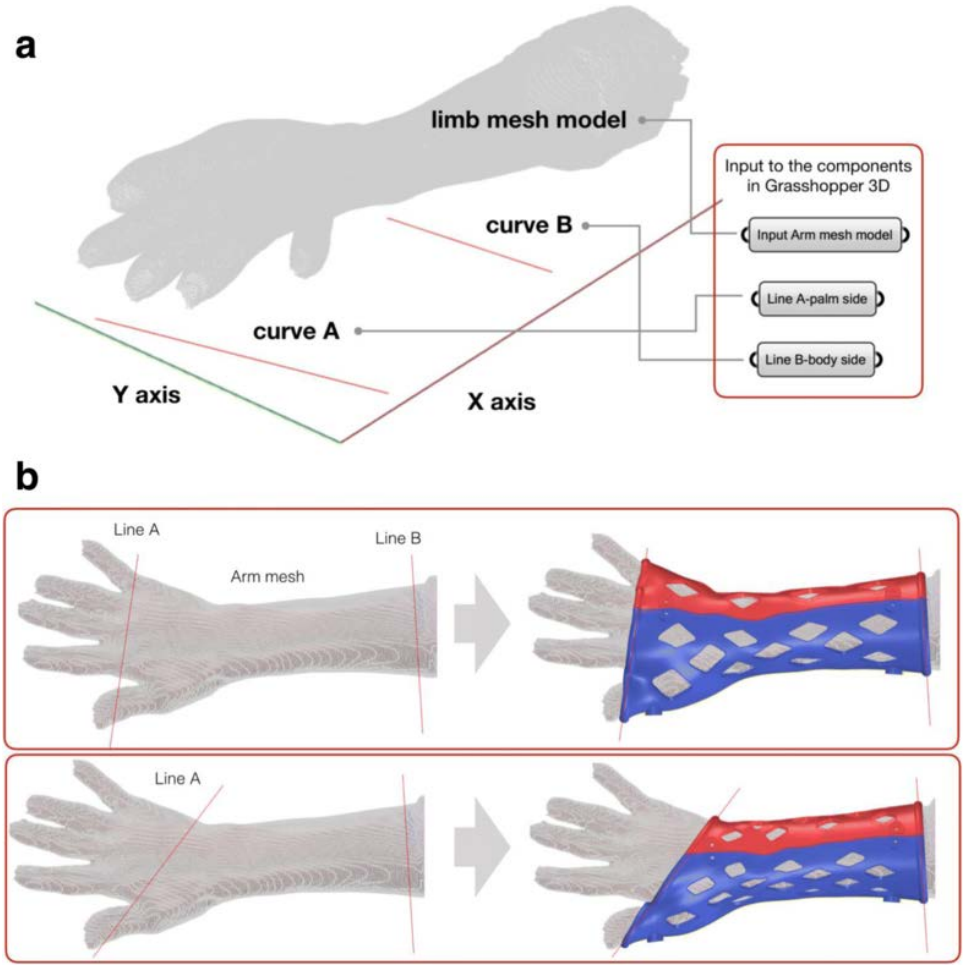


Fig. 6.6. Input stage and guideline. **a**. The limb mesh model is placed upon XY plane along X-axis with the palm facing up. The curves are drawn on XY plane. Select the 3 geometries and input to the parametric components in Grasshopper 3D. **b**. Samples of input curves and corresponding generated splints.

Further, based on the fracture status, the clinician can draw two lines to define the immobility area from the top viewport. Line A is located on the side against the palm while Line B is located on the side close to the body. As previously mentioned, holes and deformations that occur between fingers could easily result in failure during subsequent construction of the basic covering surface. Construction of curves must, therefore, avoid generation holes and deformations near limb-model edges. Furthermore, thumb fixing is necessary in immobilization treatments; to address this concern, a procedure developed for fixing thumb was incorporated in this study, thereby facilitating the palm opening to fix the thumb[68,70]. To serve as input to the finger-fixing situation, line A can cross the thumb web-space, as depicted in Fig. 6.6(b). Once the two curves are drawn, each could be assigned to the two input components in Grasshopper 3D and output to the next modeling stage.

Basic-surface construction

Once clinicians complete the input stage, the system generates the basic surface as per the process depicted in Fig. 6.7. The analytical surface, which covers the affected limb, forms the critical foundation for the splint model. The clinician can examine the status of lines A and B projected onto the limb and the way they wrap around the limb from a perspective viewpoint.

For simulation of limb swelling, the mesh model is offset by approximately 2–3 mm (Fig. 6.7(a)) [30]. Several gradual lines are generated in the immobility area between

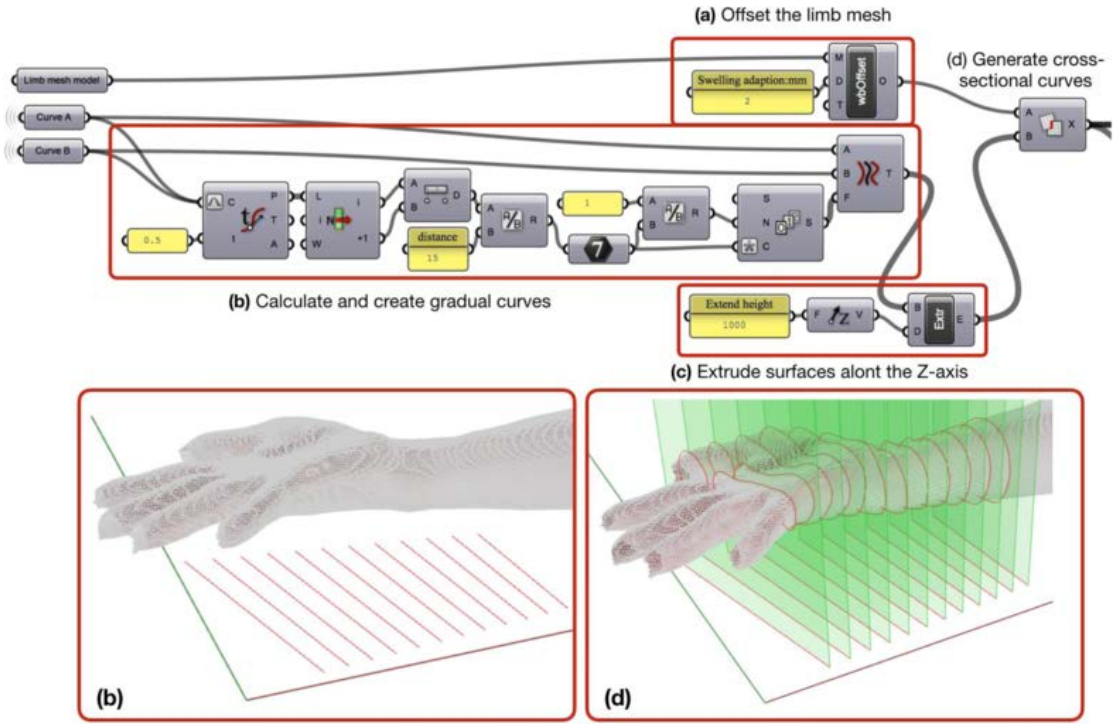


Fig. 6.7 Generate cross-sectional curves. **a.** Offset the limb mesh by 2 mm distance, **b**. Calculate and create gradual curves, **c.** Extrude surfaces along the Z-axis, **d.** Generate cross-sectional curves.

the two input lines, as depicted in Fig. 6.7(b), and their distribution density is determined based on the splint length. The spacing between the lines, as observed in this study, was of the order of 1–2 cm. The density level was sufficient for displaying most arm features; in the case at hand, 12 curves were inserted. The gradual lines extend upwards, as surfaces along the Z-axis, to intersect with the limb and subsequently generate cross-sectional curves for the U input of the network component in Grasshopper 3D (Fig. 6.7(c, d)).

If line A is drawn across the thumb web-space, this implies that dual cross-sections of the palm and thumb may appear in few projections near line A. Network modeling, however, allows projections of only single cross-sections. A procedure was, therefore, designed to merge together dual cross-sections and fix the thumb by means of a small gap, as depicted in Fig. 6.8. Upon detection of dual cross-sections, a line would pass through central points located on separate cross-sections and offset on both sides with distance of 5 mm as a rectangle (Fig. 6.8(a, b, c)). A new shape would, therefore, be obtained, via combination of the rectangle and connected cross-sections, and subsequently smoothed by means of the “Interpolate Curve” command (Fig. 6.8(d)). The shapes, thus obtained, would replace dual cross-sections appearing in the U input of the network component, and the design of a slim gap between cross-sections can be used to fix the thumb (Fig. 6.8(d)).

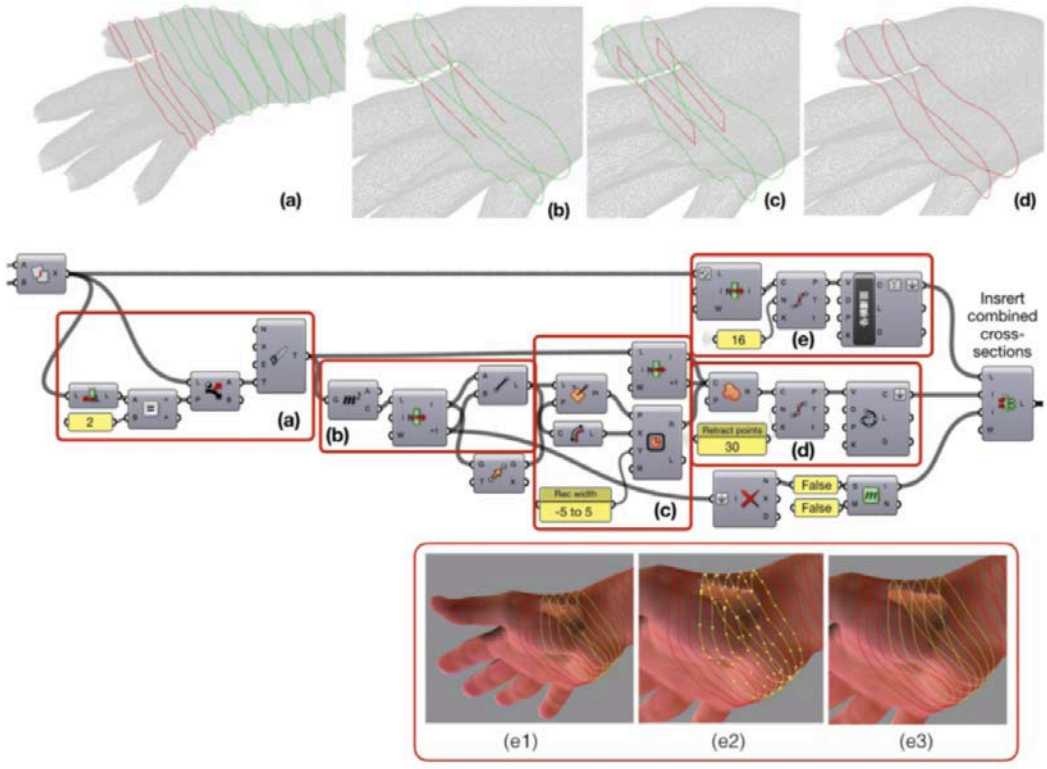


Fig. 6.8 Regenerate and fix curves. **(a)** Detect dual cross-sections, if the amount geometry equals two. The first two sets, red curves are picked. **(b)** Connect the central points of cross-sections. **(c)** Generate rectangles connect cross-sections. **(d)** Combine rectangles and cross-sections. **(e)** Fix the scan flaws by extracting points and regenerating curves.

However, there may exist modeling flaws in the arm scan, such as presence of a hole in Sample A, as depicted in Fig. 6,2(b), which could result in the presence of unclosed curves at the intersection; these curves could, in turn, generate serious distortions on the basic surface(Fig. 6.8(e1)). To fix this problem, 16 points extracted from the unclosed curve could be used to regenerate the closed curve through use of the interpolation command (Fig. 6.8(e2, e3)), and the corresponding repaired cross-sections could generate the entire covering surface. Such techniques [76,77,80] help overcome issues encountered during scanning. However, if the observed hole is large or if the immobilization area overlaps with the edge, there still exists a chance that the covering surface would be distorted. In such situations, the clinician can fix the problem by slightly moving the curves or simplifying them by using fewer defining points to avoid generation of a distorted surface.

After the cross-sectional curves are ready, extreme points corresponding to each section on the XZ and XY planes were extracted to form curves for the V input (Fig. 6.9(a, b)). The network component can generate a parametric surface within the immobilization region (Fig. 6.9(c)). Cross-section curves run along the U direction of the surface while long edges run along the V direction.

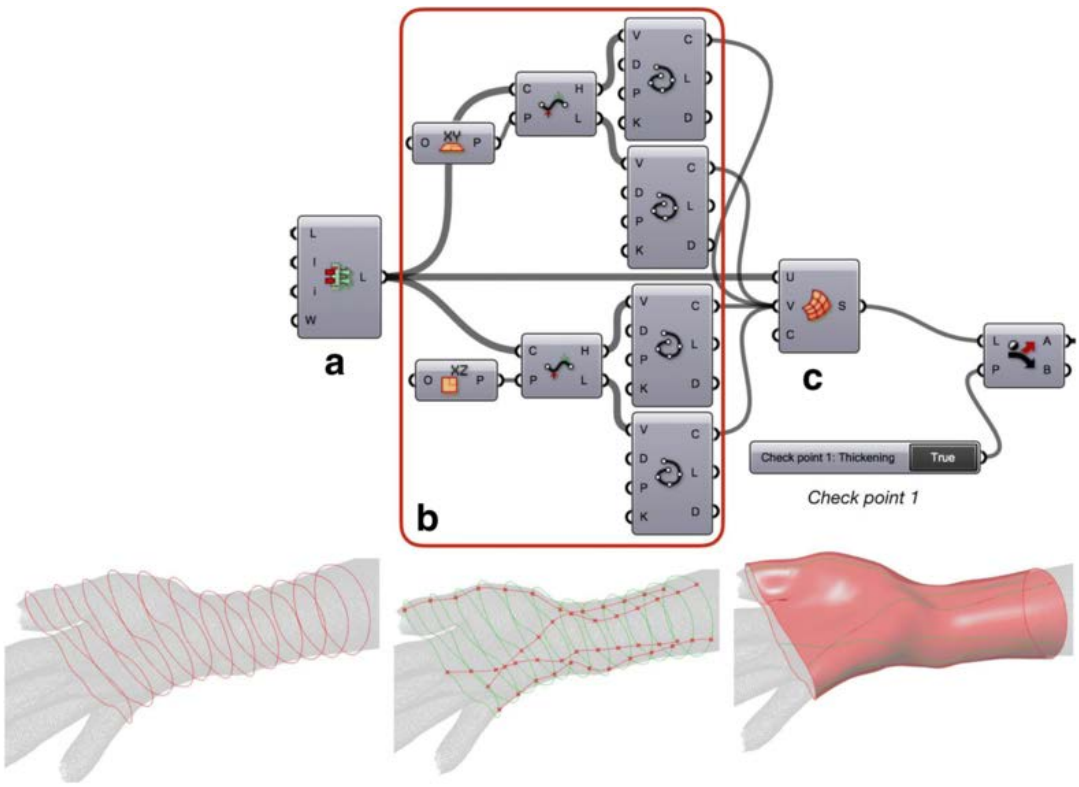


Fig. 6.9 Generate covering surface. (a) Cross-sectional curves for U input of Network component. (b) Extreme points on XZ and XY planes of each cross-sectional curves are extracted to form curves for V input. (c) Parametric surface generated by Network component.

Division and thickness generation

This step divides the covering surface into two or three surfaces covering the same area based on the overall model size. A shell with a certain thickness is grown over each surface (Fig. 6.10, 6.11). Thickness of the shell depends on the divided surface area and printing experience in order to attain the minimum required strength (Fig. 6.10(a)). Also, dividing the splint into two or three parts helps reduce the total printing time if multiple 3D printers are available. The dividing strategy is based on the trade-offs involved between the desired model strength and printing time.

- The wrist-splint default design is a two-part set, wherein the system evaluates the square measure of the basic surface and divides it into three equal parts if the total area is greater than a specified reference value, which in this case, was set as 260 cm², as depicted in Fig.6.10(b, c). The said reference value nearly equals the square measure of the covering surface of an adult palm. A larger splint used for ulnar-radius fractures is also divided into three equal parts. The system divides the edge length along the U-direction into three domains, as depicted in Fig.6.10(d1, d2), and extracts isoparametric subsurfaces. Different colors are used to distinguish between the three surfaces depicted in the figure. If the splint area assumes a value nearly equal to 260 cm², the clinician can adjust the size of the referred area to determine the portion.
- Splint thickness are calculated through use of the Remap component (Fig.6.10(a)) per the splint area, which may be as small as a child's palm or as large as an adult's forearm, i.e., ranging from 150–600 cm². Based on the area domain under consideration, the splint thickness ranges from 2.8–4 mm. This conversion, however, represents only a rough estimation, and accurate calculation of the surface thickness that provides sufficient strength to the model requires further mechanical validation.

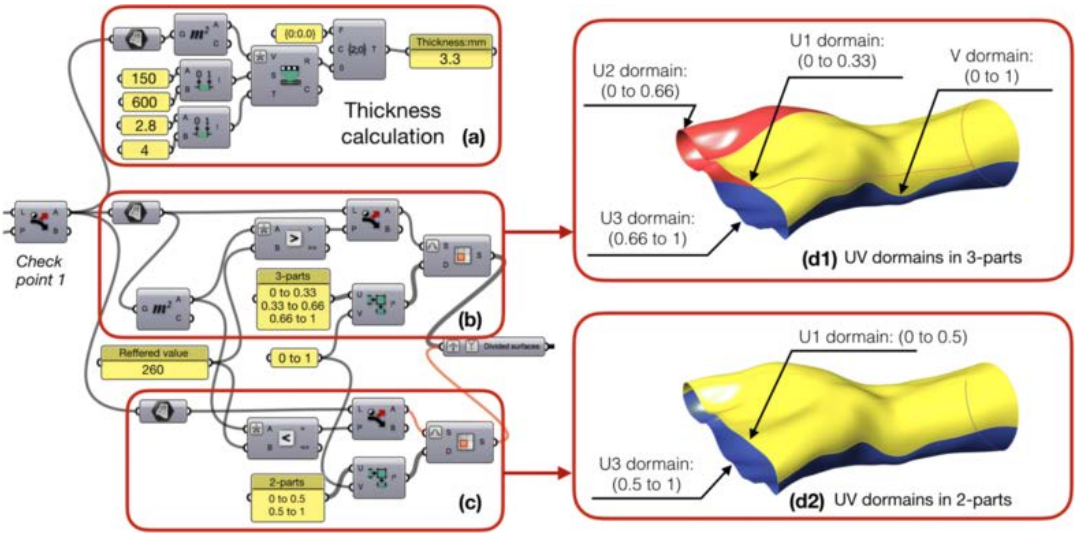


Fig. 6.10 Thickness and surface division.

- After determination of the surface thickness, peripheral surfaces are offset by the system, with respect to divided surfaces, by this distance. The edge-line of the two surfaces generates a band-shaped surface through use the “Sweep 2 rails” command. A solid shell is formed when the two surfaces are connected by means of the sweeped surfaces (Fig. 6.11(a, b, c)).

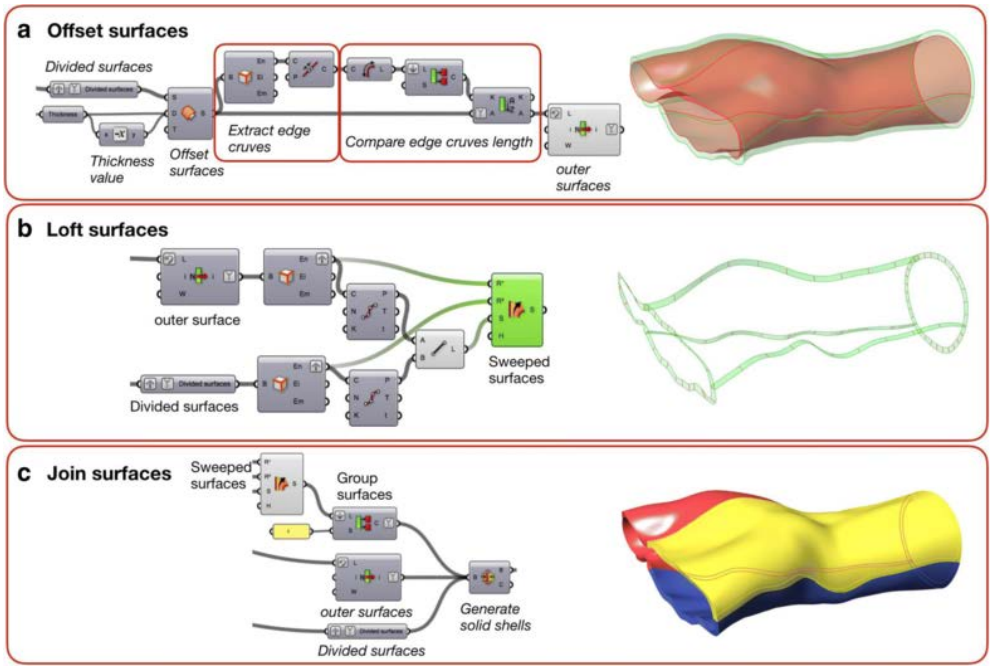


Fig. 6.11 Generate solid shells. (**a**) Offset surfaces. (**b**) Loft surfaces. (**c**) Join surfaces.

Lattice pattern and structure

In this step, a 2D preview of the lattice pattern (Fig. 6.12) is generated by the system and subsequently projected onto the shell.

- The system uses a diamond tessellation array to generate the lattice pattern, which—if the model is placed in the vertical orientation—serves to reduce both, the amount of support material consumed and printing time.
- In the 2D pattern preview, average lengths of the U and V edges—U_a and V_a, respectively—corresponding to the three divided surfaces are used as the width and length, respectively, of a 2D rectangle (Fig.6.12(a1, a2)), and offset an inner one with the M margin. After projection, the spacing from the M margin generates an external frame around the lattice structure, and the diamond tessellation pattern is generated within the inner rectangle.
- The tessellation pattern is generated by the “Diamond Panel” component in Grasshopper 3D and required inputs—the U and V divisions. The diamond array within the pattern is determined by how the rectangle is divided by oblique lines along U and V directions, and amounts of diamonds are in proportion to Ua and Va of rectangle. In the sample depicted in Fig.6.12(a1), U and V divisions are given by U_a/20 and V_a/28, respectively. These coefficients are, however, not absolute, and the rule

is to reduce the support material generated within the lattice structure during printing. U/V division numbers used in this example were set as five and seven, respectively.

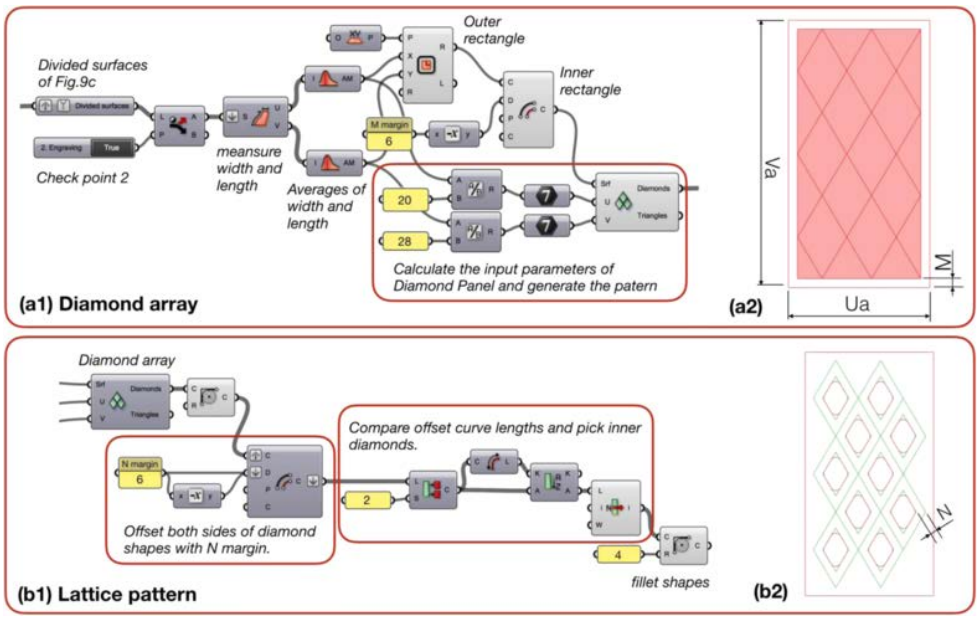


Fig.6.12 2D Lattice pattern—(a1) Program of generating diamond array pattern (a2) Diamond array pattern preview; and (b1) Program of generating structural pattern; (b2) 2D lattice pattern preview

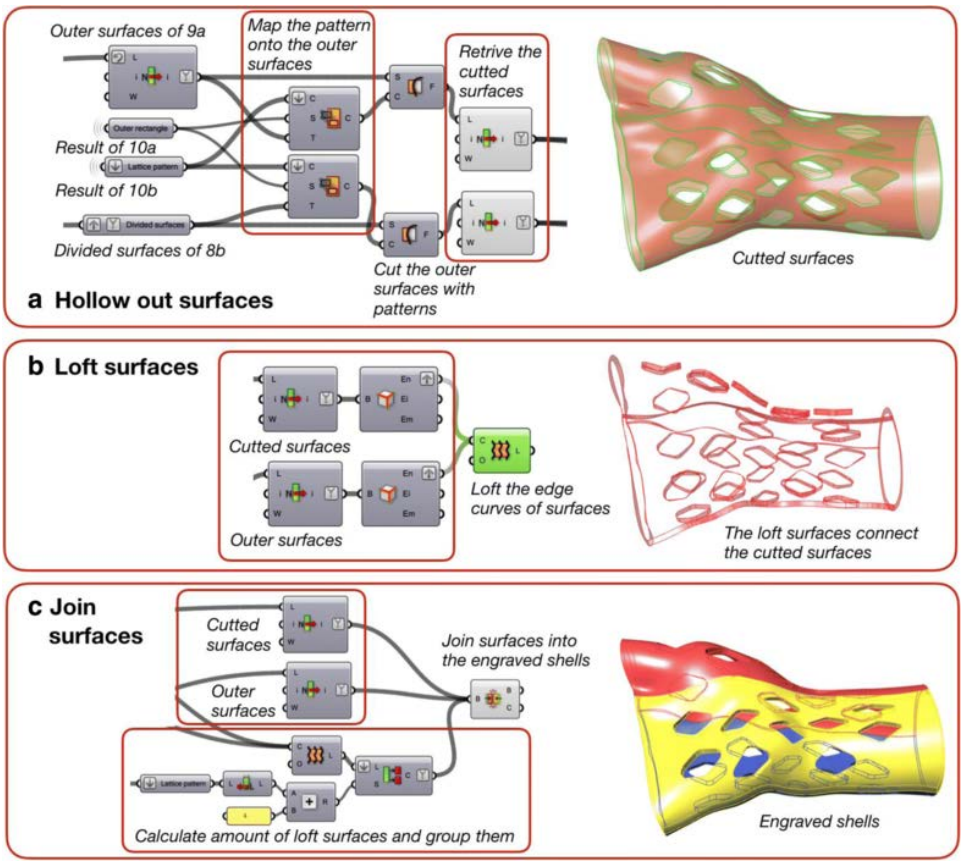


Fig. 6.13 Engraving process (**a**) Hollow out surfaces. (**b**) Loft surfaces and connect cute surfaces. (**c**) Join surfaces Mapping pattern on the shell; and (c) Engraved shells.

- Each diamond in the tessellation was offset by the N margin and provided width to the structure truss.
- Figure 6.13(a) depicts the 2D pattern projected onto the inner and outer surfaces of each splint shell. The pattern could be used to cut holes in the lattice. The loft command can be used to create surfaces between two-hole edges, as depicted in Fig. 6.13(b). Finally, all remaining surfaces, including lofted ones, could be joined together to form a solid latticed shell (Fig.6.13(c)). If the system fails to engrave the shell, values of parameters U and V in the divided area could be decreased to enlarge pattern holes, thereby avoiding generation of tiny holes that cause operation failure.

Rounded-edge and screw-seat generation

This is the last step involved in splint-model generation, and generates two important features—rounded edges, for preventing skin abrasion, and M3 screw seats, to facilitate the assembly of different splint parts (Fig.6.14). The program depicted in the figure corresponds to that of the sample comprising three parts.

- For the round edge, two tubes were developed along the U direction edge of the splint surface through use of the “Sweep” command (Fig.6.14(a)). Two isocurves of edge surfaces on the U direction of each splint were extracted to serve as the sweep path, and the main segment of isocurves are extracted with the curve domain 0.01-0.99 (Fig. 6.14(a1 and a2)). Perpendicular planes at the ends of the edge lines were simultaneously defined. Two circles were drawn on these planes, with diameters roughly large than the splint thickness about 1.5 mm, to serve as tube cross-sections (Fig.6.14(a3)).

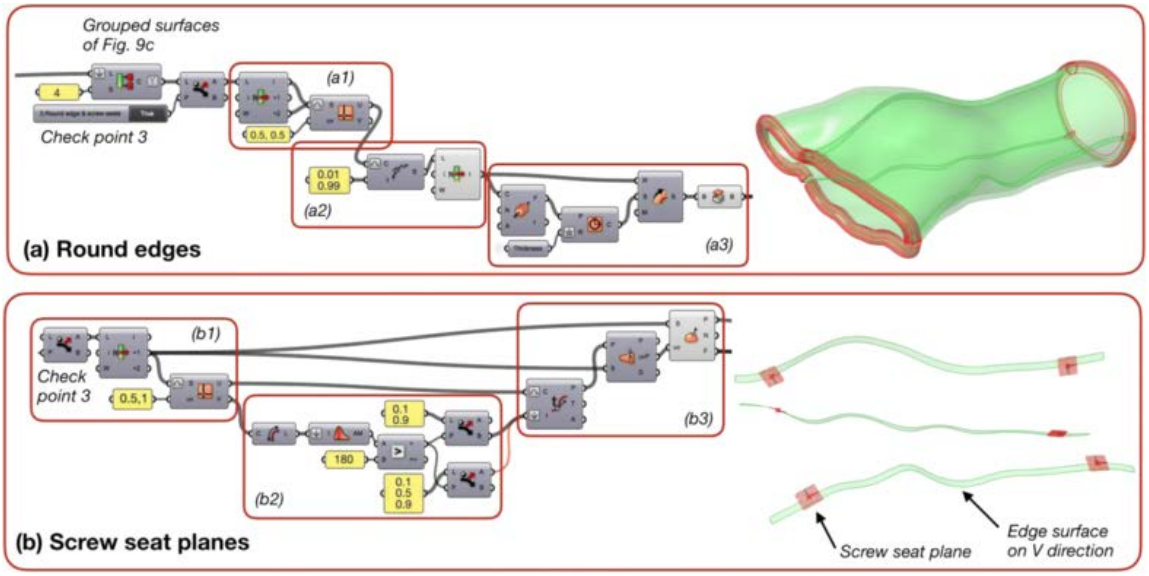


Fig. 6.14 Generation of round edges and screw seats—**(a)** Round edges. (a1) Extract isocurves from front and backward edge surfaces, (a2) Extract main segments of isocurves on U direction, (a3) Generating round edges on the splint edges by Sweep command; **(b)** Screw seat planes. (b1) Extract isocurves of edge surfaces on V direction (b2) Measure V edge lengths for Judgement of adding additional screw seats; (b3) Generate screw seats onto edge surfaces.

- The splint was assembled by fastening several M3 screws. Several planes are set for placing the screw seats to precise positions on edge surfaces of V direction, The screw seat plane was duplicated from the original position onto two points on isocurves with parametric position 0.1 and 0.9 on each V edge surface, as depicted in Fig.6.14(b1, b2). If the V-edge length exceeded 180 mm, an extra screw seat plane was added at midpoints along V edges.
- An embedded model of the M3 screw seat, part O and I were installed on the XY plane (Fig.6.15(a1 and a2)) and duplicated onto the planes. The screw seat was created via Boolean subtraction of two parts, wherein the part I was subtracted from the part O, thereby creating space for containing screw nuts. The screw sets work by constraining nuts, since the screw threads were too tiny to be printed in the prototype. Finally, each splint shell was combined with two tubes and 4–6 screw seats through use of the Boolean union and difference commands (Fig.6.15(b)).

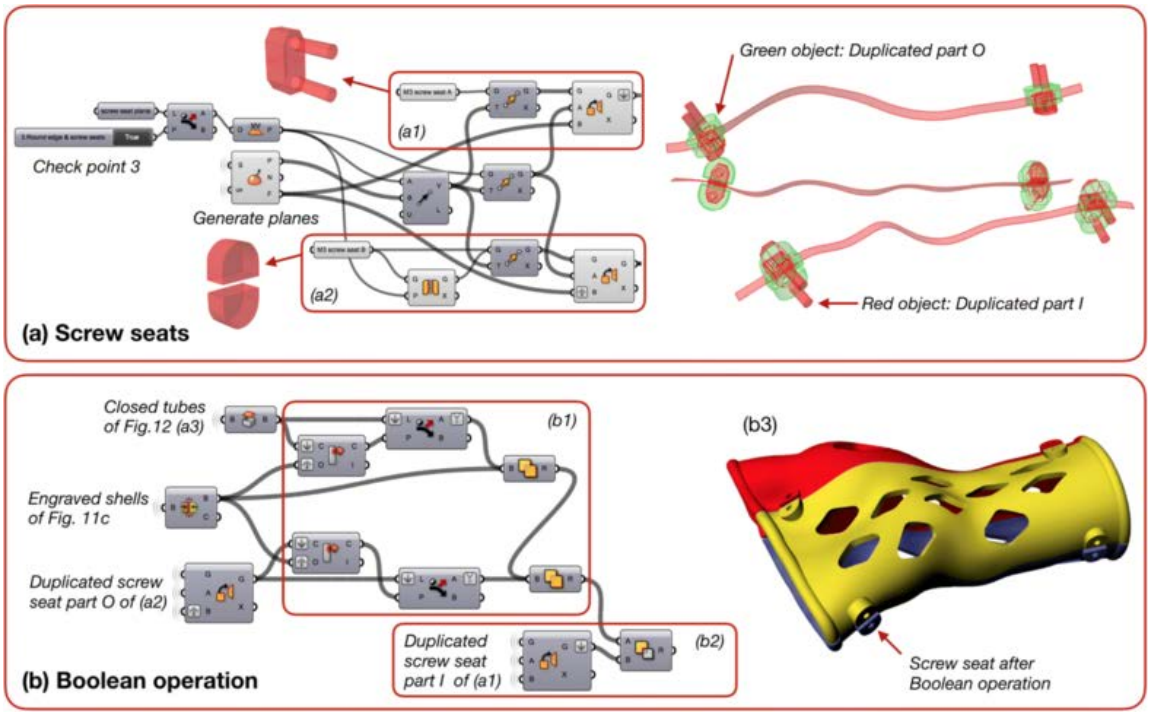


Fig. 6.15 Generation of screw seats and boolean operation. **(a)** Screw seats (a1) Screw seat part I is embedded in the Brep components and duplicated to the planes (a2) Brep component of Part O is duplicated on the same planes; **(b)** Boolean operation (b1) Union Boolean of part O, engraved shells and round edges (b2) Boolean subtraction of duplications of part I and engraved shells (b3) Final splint model.

The entire splint-modeling process of the system can be described by means of the above steps. The proposed system can, therefore, assist the clinician in generating a feasible splint model within few minutes. However, system failures are still possible. As such, it is important to explain to the clinician the operating principles of the system and remedial measures to be employed during different stages in the event of a system failure.

Customized interface

Based on the workflow, the integrated interface of Rhino and Grasshopper was customized (Fig. 6.16), and it was simplified to reduce the learning period for the clinician. All menu, toolbars and panels in the Rhino interface were removed, and only 4 viewports and the Lines tool are required for clinician to draw a quadrangle and evaluate the model state visually (Fig. 6.16a). On the Grasshopper interface, the main node-based program and menu are hidden (Fig. 6.16b), and the clinician does not need to know how the program works. There are 7 necessary components, which are displayed and numbered according to the workflow. The first two components can receive the data from the limb model and the quadrangle by setting them in their component menus, and then generate the covering surfaces. The next 5 True/False toggles control the arm display, main data flow of the model generation and final model export, and Toggles 4 to 6 can output True values and an updated orthosis model.

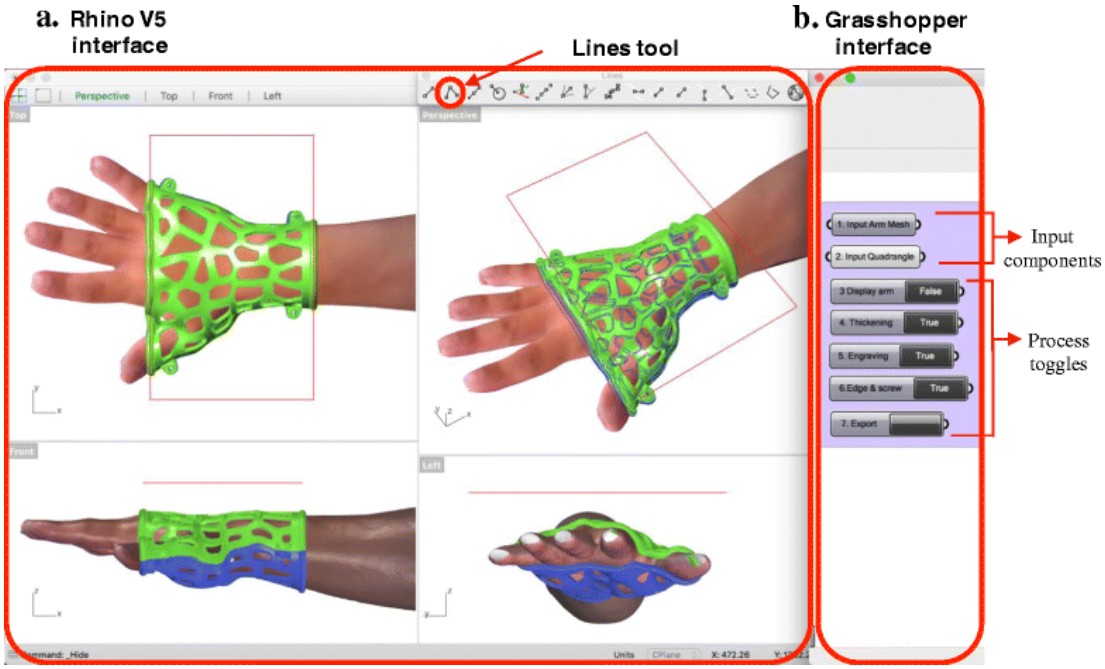


Fig. 6.16 Customized interface of Rhino and Grasshopper.

6.3 Experiment 2: Filtering face-piece respirator

6.3.1 Introduction

The filter face-piece respirator is not a typical medical device for patients in the reference investigation, such as the splint or prosthesis, but it is a personal protective device for medical staff. I chose the device as a subject in my experiments for three reasons: 1) medical staff have strong demands for personalized respirators, 2) digital fabrication technology can solve the requirement of personalization, and 3) infection control practitioners (ICP) can customize the devices for medical staff to improve the fit test results.

This experiment was executed under Fab Nurse project lead by Prof. Shoko Miyagawa of the Faculty of Nursing and Medical Care and was associated with Infection Prevention Strategy Unit of the International Goodwill Hospital in Yokohama during 2017. In this experiment, I selected the filtering face-piece respirator as the customizable product, and the users are healthcare workers (HCW). ICP plays the role of ICP in this case. The overview of actor framework is visualized in Fig. 6.17.

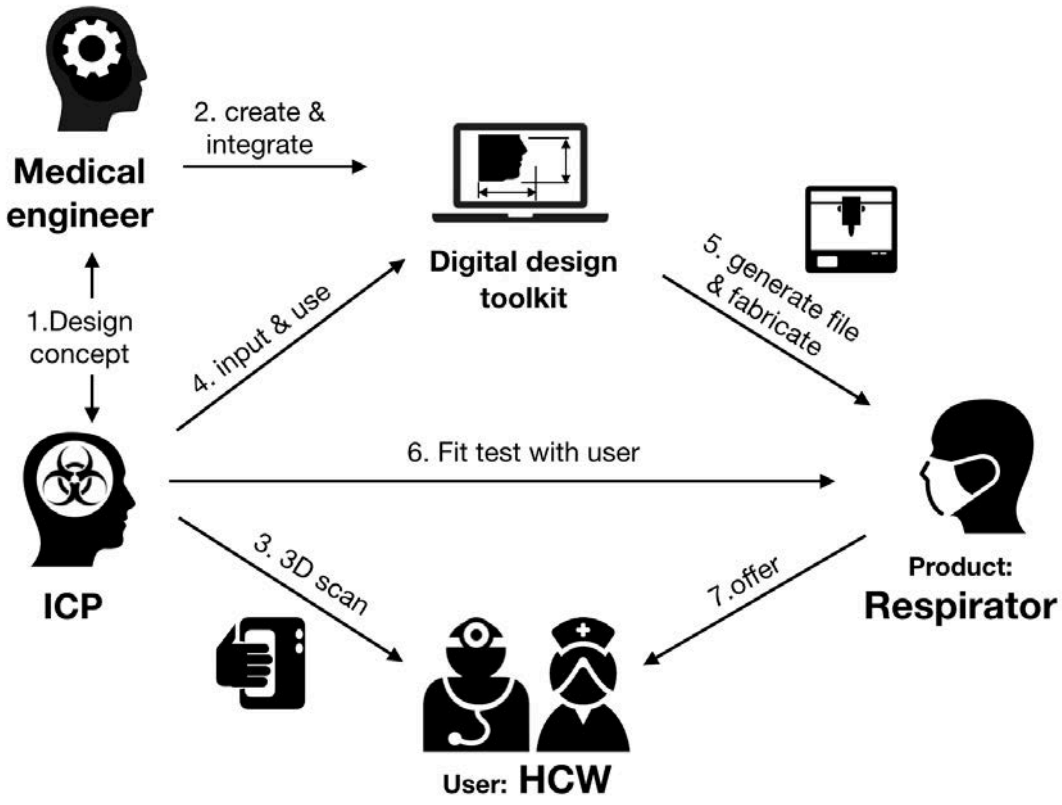


Fig. 6.17. Framework map of Experiment 2.

Motivation

In this experiment, hospital employees are strong demanders of personalized protective device, especially HCW who contact patients directly. They work in a medical environment and have long exposure to highly infective hazards. Personal protective equipment can protect them from the spread of illness, and filtering face-piece respirators are frequent devices used to prevent inhalation of infectious agents. The level of protection provided by a respirator is determined by how well the face piece fits to the worker's face, and the seal between the respirator and user's face is the most critical and uncertain factor that affects the protective performance [81-83]. Currently, disposable N95 masks are the most common choice.

In America, Occupational Safety and Health Administration (OSHA) requires workers to do the fit test annually to ensure that the respirator fits correctly, and no leaks exit [84-87]. According to the fit-testing protocols of OSHA, two kinds of fit-testing protocols are available: a quantitative fit test (QNFT) and a qualitative fit test (QLFT) (Fig. 6.18)[88-90]. According to the QNFT protocols of OSHA, the subject should complete a series of motions of the head and face during the test, and a challenge agent is administered outside the face piece and the presence of the agent is detected and counted by an instrument (Fig. 6.18A). A fit factor is used to express the results of a quantitative fit test, namely, the ratio of the test agent concentration outside the respirator to the test agent concentration inside the respirator. However, wearers have different facial features, and disposable masks of mass production cannot achieve a very close facial fit for everyone, with the standard design. In a quantitative fit test of 209 subjects from two hospitals, the results showed that 63.2% of the subjects obtained a fit factor greater than 100, which is the fit test pass/fail level for filtering face-pieces recommended by the respirator authority in America [91-93].

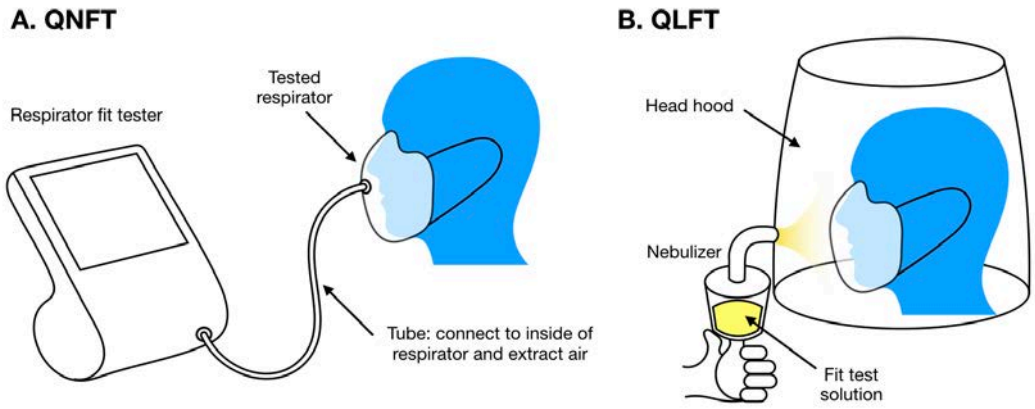


Fig.6.18. Placement of fit tests. **A**. QNFT. **B**. QLFT.

Now, 3-D scanning, 3-D printing technology, and biocompatible material availability provide an opportunity to realize a wearer-specific respirator. The 3-D scanning can catch the precise facial surface for subsequent modeling material to create a good fit of the contact part. Using the medical-grade filament and a commercial FDM printer can produce such a respirator in a few hours. Based on the similar experience of customizing medical device, the 3-D-printed respirator has the chance to improve the seal tightness and wearer comfort.

In addition, the tested ICP were ideal design agent for this experiment. Usually, ICP are responsible for the prevention, investigation, observation and reporting of infectious diseases, so ICP is also in charge of respirator selection for HCW and the annual fit test record. Compared disposable N95 mask, the customized respirator may help ICP to improve the fit-testing result and save workload from the management by providing various respirators.

Challenge and objective

Again, the main challenge is the respirator design is a time-consuming process that requires significant CAD experience, and no qualified CAD expert was available in the hospital; nor was an appropriate CAD tool available to aid ICP in dealing with the design of mass respirators for the healthcare staff. The objective was to develop a perfect-fit respirator design and its semiautomatic modeling process based on the requirements of the fit test and to help the ICP with a respirator design task efficiently without deep CAD involvement.

6.3.2 Method

Preparation

A handheld scanner, Sense (3-D Systems), was used to scan and was able to output a mesh model of the face. The scanner was affordable and lightweight, and its software offers the basic function of background clipping. Five scanned face samples were obtained from adult volunteers and labeled as A to E (Fig. 6.19): two males (C and D) and three females. Extra postproduction procedures after scanning are not necessary, and only simple clipping was performed on the masks to remove unnecessary body

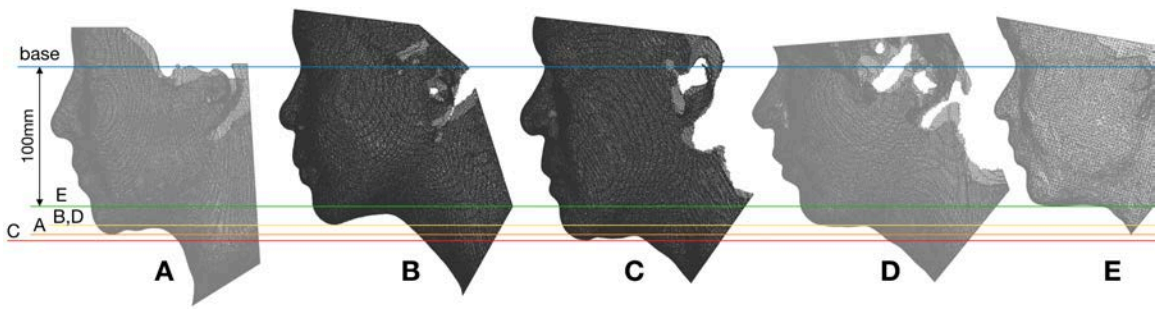


Fig. 6.19 Five facial samples collected form adult volunteers.

regions. These samples were aligned to a baseline that passes the eyes on the side view to emphasize the differences in the face sizes. The scanned anatomic range should completely include the eye, nose, mouth, cheek, jaw and throat. ICP should ask the wearer to repeat the movements in the fitness test and observe the wearer's facial muscle movement to understand the ideal covered range. The scanning processes of these samples followed the above mentioned principles.

Material

Considering the filter availability, we selected *3M 7711* (3M) filter for the standard material of our respirator, and any round-pad disposable filter with a diameter 86 mm is also compatible. Fabrial-R (JSR) filament, the medical-grade filament that matches *ISO-10993-10* standards, was used for printing the customizable part. In the thin thickness, the filament has the good performance on flexibility and softness.

Respirator features

The respirator design generated by the design tool was assembled from 4 components in the order indicated as follows: the main body of the customized mask, round filter, filter fixer, and exhalation valve (Fig. 6.20). Only the main body is customizable and printed by the Fabrial-R filament, and the other components are mass produced for the standard model.

• Covering surface: The covering surface of the respirator is extracted from the scanned area around the nose, mouth and cheek of the wearer's face model, marked as a red range inside the mask and on the scanned model in Fig. 6.20c, and it efficiently provided a snug fit and respiratory protection for the wearer while maintaining an effective seal. Considering that the required movement of fit test, such as the speaking and head turning, may trigger the facial muscles and neck, and cause temporary air

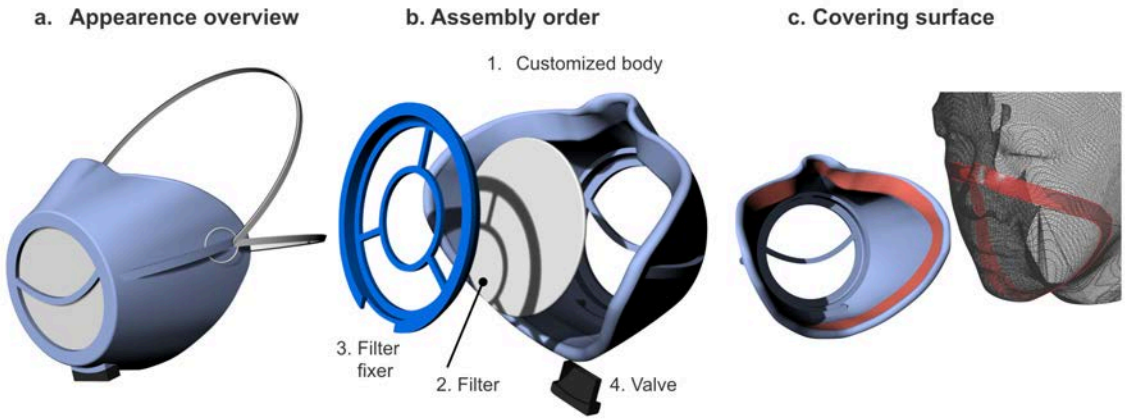


Fig. 6.20 Respirator design. **a**. Respirator appearance **b**. components **c**. Contact area on wearer's face and inner surface of respirator .

leakage, the determination of the covering surface should avoid these areas. The ideal covering surface should cross the nose ridge, pass the underside of the eye, cover the cheek as possible, and pass the backside of the chin.

- Filter assembly: The filter is gripped by a front-end structure of mask and a piece of fixing ring, and the fixing ring is locked by the inserted exhalation valve. When replacing the filter, ejecting the valve can release the fixing ring and remove the filter. The design ensures that air only enters into the respirator through the filter and exits though the valve. When customizing the respirator, the filter assembly and valve should be placed at a distance from the wearer's nose and chin to prevent skin abrasion.

- Exhalation valve: The valve is placed at the downside of respirator near the wearer's chin and faces wearer's nostril. The valve allows the wearer's breath to escape from the mask without allowing airborne particles to enter and helps keep the user comfortable by reducing heat and humidity inside the mask. In the assembly, the valve can stock the filter fixer when it is inserted into the respirator.

- Rounded edges: The edges of the splint are designed as tubular shapes to prevent skin abrasion by sharp or rough edges.

Modeling workflow

Based on the above features, several different modeling sequences were tested by manual operation for building the same respirator in Rhinoceros 3-D, and a modeling workflow was determined, as shown in Fig. 6.21. The modeling system was divided into five stages and converted to Grasshopper. The five stages include (Fig. 6.21a) the following: Import face model, calibrate and assign to modeling program, (Fig. 6.21b); Define covering surface, (Fig. 6.21c); Define filter assembly (Fig. 6.21d); Generate cross-section (Fig. 6.21e); and Generate printable model. In the whole process, the ICP only operates the input content, including the facial model, the curve that determines covering surface, two points that decide the position of filter assembly, and the design tool offers visual feedback according to the input adjustment in real time. The respirator model gradually takes shape as the modeling procedure progresses. Other default

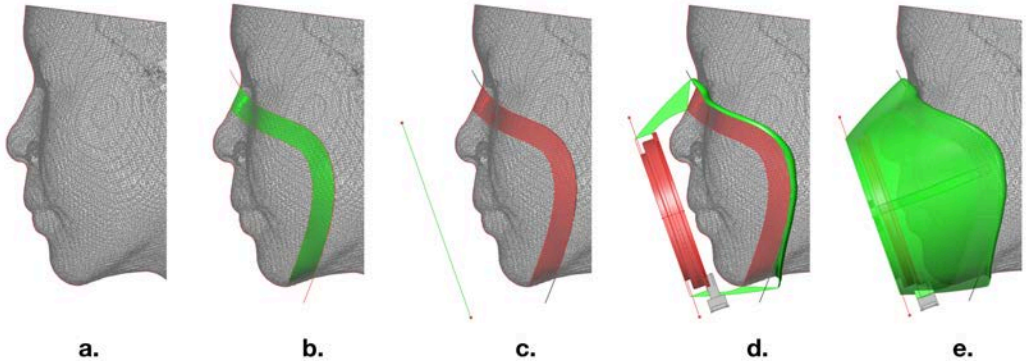


Fig. 6.21 Modeling steps.

parameters have been tested iteratively and optimized. The input methods in Grasshopper and detailed modeling mechanisms of five stages are described as shown below according to the customization process.

Importing the scanned face model and calibration

When importing the scanned face, the mesh model may appear in the Rhino 3-D space with random angle and position; therefore, the ICP may need to move it to the appropriate position and rotate it to face the XZ plane straight on (Fig. 6.22a). The YZ plane should be on the mirror plane of the face. A set of guide lines colored in purple are provided on the front viewport; these indicate the symmetrical intersections of the pupils and the two ends of the mouth. ICP can evaluate the distance between the model pupils or mouth width to move the model and keep the YZ plane overlap on its mirror plane (Fig. 6.22b). After the face model is at the ready position, ICP can select it and assign to a mesh component in Grasshopper via the component menu (Fig. 6.22c); then, the model data can pass to the subsequent modeling procedure.

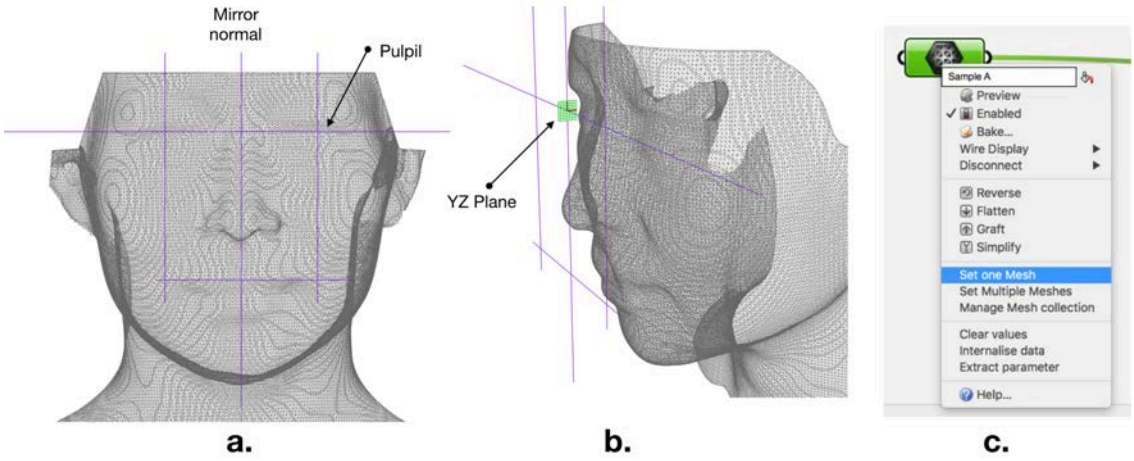


Fig. 6.22 Calibration of imported model.

Defining the covering surface

In this step, the ICP needs to draw a landmark curve on the side viewport to decide the area covered by the respirator. During the scan, the ICP should ask the wearer to do the head turn, nod and speak—those movements in the fit test—and observe muscle movement on the wearer's face to evaluate the covering range. The covering surface is defined and activated by a planar curve, Curve X1, that is drawn on the side viewport, and the ideal curve should avoid the muscle around mouth and neck (Fig. 6.23a). After the curve is completed, the ICP should assign this curve to a curve component into Grasshopper (Fig. 6.23b). Then, the program uses the curve to offset Curve X2 in its left side with a 12 mm distance (Fig. 6.23c). These two planar curves extend from the X-

axis to intersect with the face model (Fig. 6.23-D) and generate the cross-section curves. The curves can be mirrored and connect with another half as closed 3-D curves, Curve X1' and X2' (Fig. 6.23e). For visualizing the covering surface, 30 points are extracted on Curve X1' and X2' separately and connected to form 30 lines, thereby generating a belt surface by network command (Fig. 6.23f). The ICP can move the control points of the curve to change the belt surface, so the program updates its shape in real time for the ICP's evaluation.

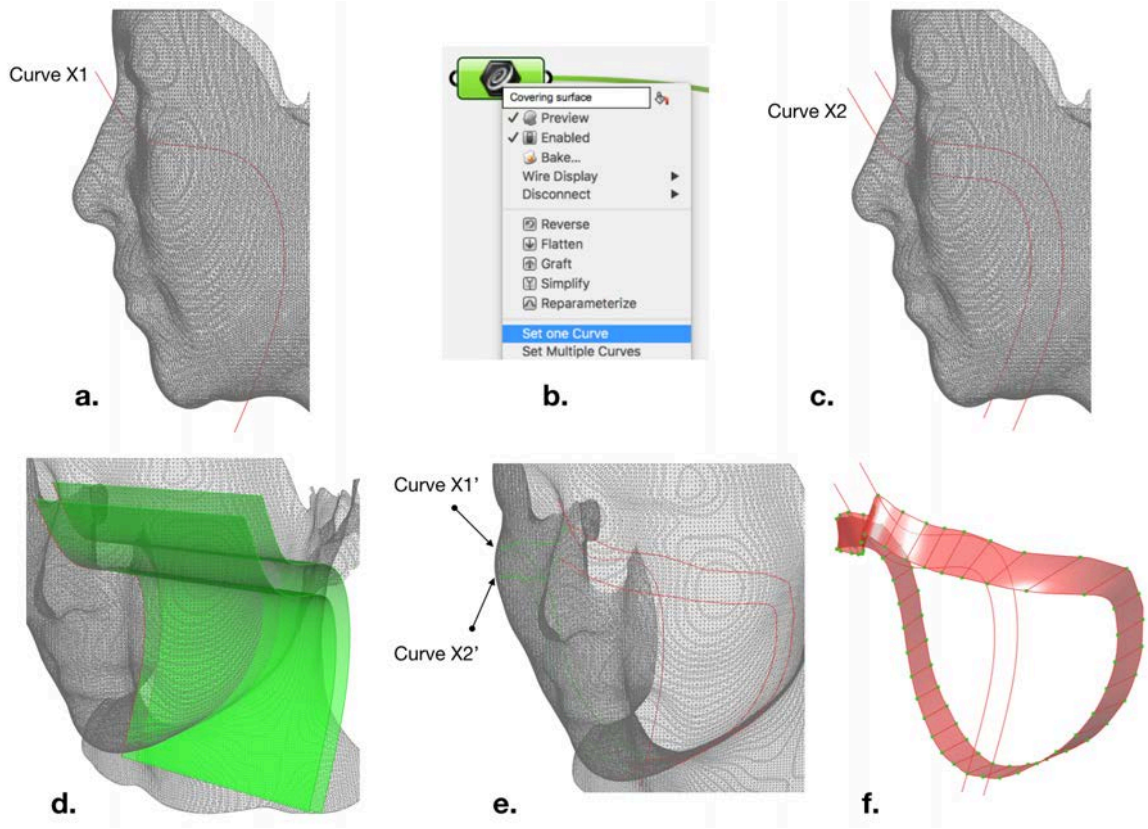


Fig. 6.23 Generation steps of contact area on the wearer's face.

Defining the filter assembly

The filter assembly includes the front end of the respirator, filter, fixing ring and exhalation valve; these are fixed structures and components installed in the program. ICP can set two points, Pt1 and Pt2 on the side viewport to decide the plane of the filter assembly (Fig. 6.24a) and can set the two points to the Grasshopper components. The program uses these two points to form a line, Pt12, and the principle used to set the points is to keep Pt12 parallel to a virtual line that passes the nasal tip, lip and chin to keep a distance. Pt12 is set as the Y-axis of the new plane, Plane F, and its midpoint is the original point (Fig. 6.24b). After the program receives the point data, the models of the filter assembly are duplicated from the original position and moved to Plane F (Fig. 6.24c). According the displayed models, the ICP can move the two points to adjust the

position and angle of the filter assembly and close the face model (Fig. 6.24d). Short distances can allow the assembly to avoid contact with the face, but unnecessary distance would increase the respirator volume and fabrication time. Although the Curve X1, Pt 1 and Pt 2 are determined, ICP can adjust them in the following stages based on the appearance of further model details, if necessary.

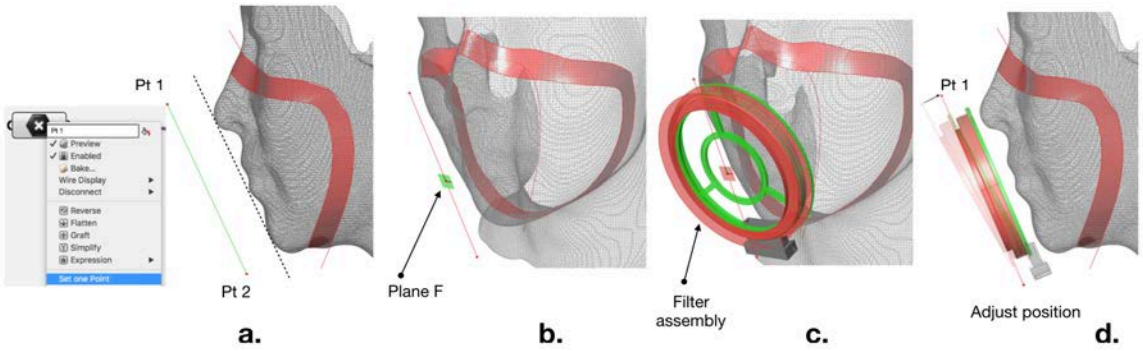


Fig.6.24 Quick setting of the filter unit by two point.

Generating the round edge

In this step, the program generates a round edge, a blended surface connects the covering surface and its offset surface, and it can prevent skin abrasion on the external edge of the covering surface. The covering surface offsets a surface with a distance of 12 mm and Surface Y, and the distance equals the thickness of the round edge (Fig. 6.25a). The external edge curve of Surface Y, Curve Y', is extracted, and Curve Y' and

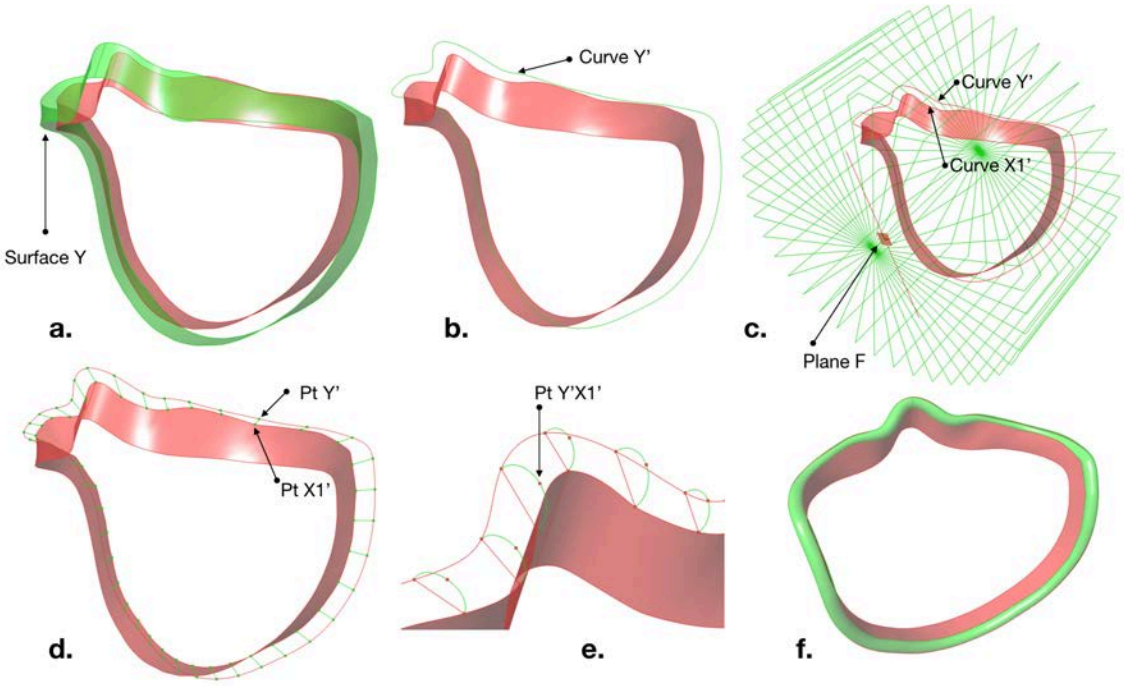


Fig. 6.25 Automatic modeling steps of round edge.

Curve X1’ are the two rail paths of round edge in the subsequent modeling process. A polar array of 30 rectangles are generated on Plane F (Fig. 6.25c), and their intersection points on Curve Y’ and Curve X1’ are, respectively, Pt Y’ and Pt X1’. Each set of Pt Y’s and Pt X1’s links as a line (Fig. 6.25d), and then each midpoint, Pt Y’X1’, makes a 6-mm move along its own Z-axis on the rectangle (Fig. 6.25e). Pt Y’, Pt X1’ and PtY’X1’ link an arc. With the Curve Y’, Curve X1 and all arcs, the round edge surface is generated by the network command (Fig. 6.25f).

Generating the respirator

In this step, the program generates two surfaces to connect the other surfaces into a solid surface. The front end of the respirator is an open surface with the edge lines, Curve Z1’ and Curve Z2’ (Fig. 6.26a). As with the similar steps to create the round edge, the program uses the rectangle array to generate the intersection points on Curve X2’ and Curve Z2’, respectively (Fig. 6.26b) and to obtain Pt X2’ and Pt Z2’ (Fig. 6.26c). Then, their midpoint, Pt X2’Z2’, makes a 2-mm move on its Z-axis and links an arc with the previous two points (Fig. 6.26d). With the Curve X2’, Curve Z2’ and arcs, the inner surface of respirator, Surface X2’Z2’, is generated between the front end and the covering surface. The same process is repeated on the Curve Y’ and Curve Z1’ to create the external surface, Surface Y’Z1’. A solid model of respirator is formed by joining the above surfaces. The respirator is fixed by the elastic band set when being worn, and a pair of grips are required on the two side of Surface Y’Z1’ to fasten the rings of elastic band.

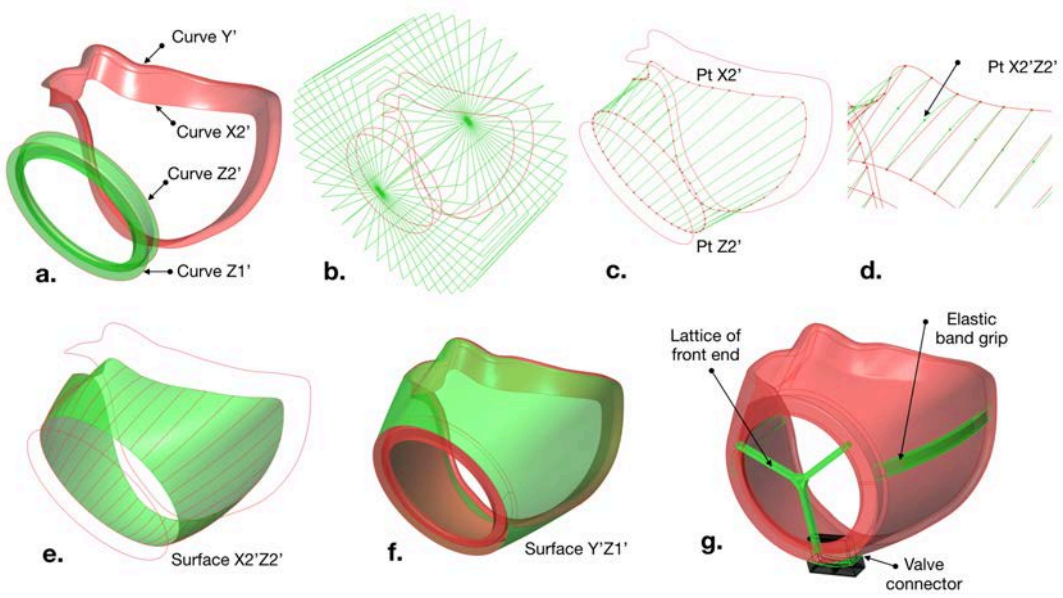


Fig. 6.26. Automatic modeling steps of mask body. **a**.Edges of front end, Curve Z1’ and Z2’. **b**. Generate intersections. **c**. Intersections on Curve Z2’ and X2’. **d**. Z movement of Pt X2’Z2’. **e**.Inner surface. **f**. Outer surface. **g**. Other functional structures.

The entire respirator-model process of the design tool is described in the above steps; the design tool can assist the ICP in generating the model within a few minutes.

Customized interface

Based on the above modeling workflow, the user interface is presented in Fig. 6.27. The left side placement includes Rhino interface for checking the model status and tool bar for drawing the curve and points, and the right side is the Grasshopper interface for the geometric settings.

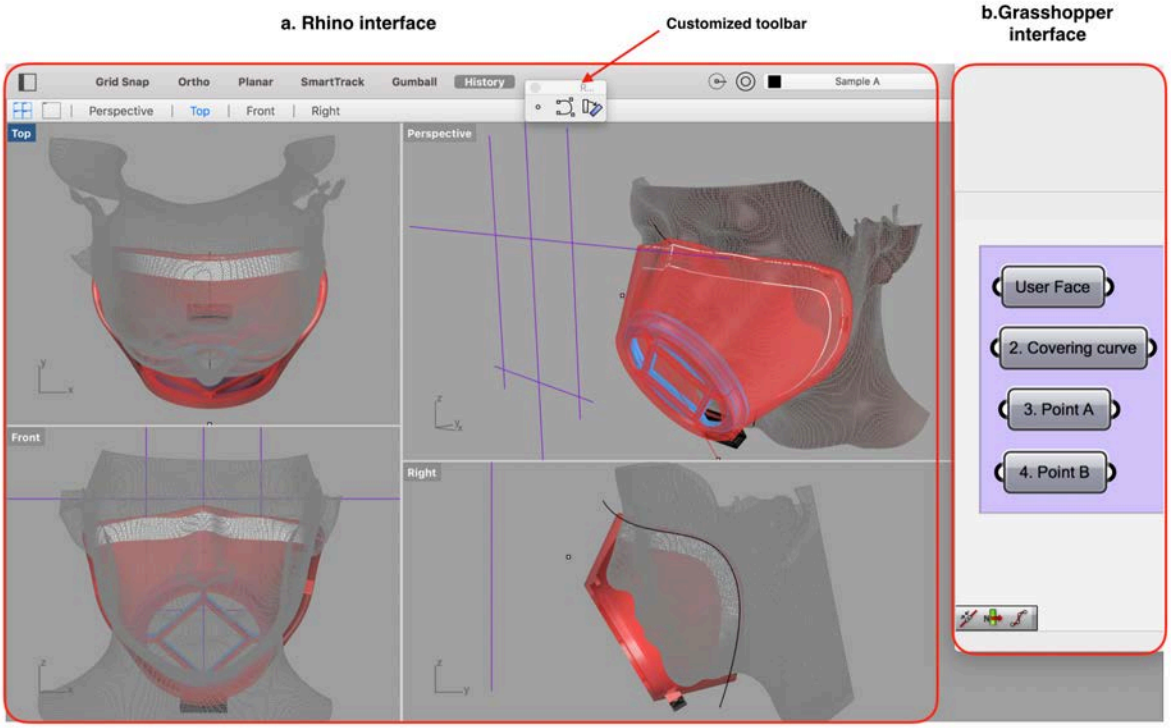


Fig.6.27 Simplified interface based on the operation process.

Chapter 7
Analysis

7.1 Introduction

In this chapter, the two modeling programs are applied on 5-10 scanned samples to generate physical models and examine their two performance indicators of the modeling program and the stability and efficiency when generating printable models.

The stability presents the success rate of generating geometrically closed models on various scanned objects and input content. The modeling process contains hundreds of components in Grasshopper, and the process may stop or crash in the modeling due to failed input between components or massive instant computations appearing in the data flow. The generated models may contain naked edges or twisted surface and cannot output printable STL file, and models that fail the union in Boolean operations with other objects will have lost necessary function or be unable to be assembled.

In the valid models, the efficiency presents the required time for generating part of the result models in the modeling process after the design agent has completed the specific input or pass parameters for the next modeling procedures. The whole time period of the design process includes the operation time of the design agent and waiting time for the program’s response. Usually, the calculation that includes mass modeling steps only takes a few seconds and reduces the design time to a few minutes from hours.

The final physical products made with output STL files are demonstrated in the ends of experiments, and detailed fabrication information is recorded.

7.2 Experiment 1

7.2.1 Stability and efficiency of generating printable models

Time required for splint-model generation

Five sample splint designs for actual fractures were generated in this study. The samples comprised a wrist splint assembled in two parts and a larger splint—that covered the palm and forearm—designed in three parts. Curve drawing and providing splint geometries as input to Grasshopper 3D usually takes 1–2 min depending on the clinician's diagnosis. The time required for model calculation at each stage for Samples A and E is included in Fig. 7.1, wherein it has been marked between model results. In the 2-part splint process, generation of the covering surface consumed 2 s while that of solid shells of required thicknesses was completed in 3 s, and so on.

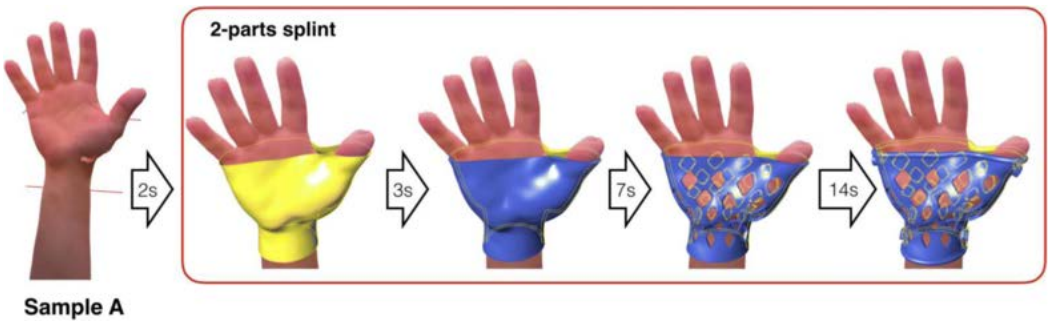


Fig. 7.1 Required time(s) for calculation in each stage of Sample 1.

The total time spent on the five samples was recorded and has been listed in Table. 7.1. Most stages took little time (few seconds), whereas the last stage, wherein round edges and screw seats were generated, lasted approximately 8–25 s. As expected, the design of the 3-part splint was observed to be slightly more time-consuming compared to the 2-part splint. The overall design process, including curve drawing and geometry input lasted roughly 2–3 mins, in most cases.

Lost-mesh fixing performance

During simulations, a small area of the mesh in samples A and E was lost owing to deficient illumination during the scanning process. The samples, therefore comprised holes measuring approximately 2×4 cm² and 1.5×2 cm², respectively, and located in the immobilization region, as depicted in Fig.7.2(a). Presence of holes lead to breaking of a few cross-sections marked by yellow curves. In both samples, the system extracted points from unclosed curves, thereby automatically regenerating closed cross-sections

(Fig.7.2(b)). As depicted in Fig.7.2(c), the covering surface generated the complete shell; during subsequent fabrication and user fitting, the repaired area did not impact the splint's fitness and/or comfort.

Table.7.1 Required time(s) for generating splint for each stage of the six samples.

		Required time (seconds) of calculation in each stage				
Sample	**Parts amount**	**Covering surface**	**Offset solid shell**	**Lattice structure**	**Round edge & screw seats**	**Total**
A	2 parts	2	3	7	14	26
	3 parts	2	4	10	25	41
B	2 parts	3	3	4	9	19
	3 parts	2	3	7	18	30
C	2 parts	2	3	3	8	16
	3 parts	2	2	4	13	21
D	2 parts	2	3	3	11	19
	3 parts	2	3	6	18	29
E	2 parts	2	3	7	18	30
	3 parts	2	4	8	20	34

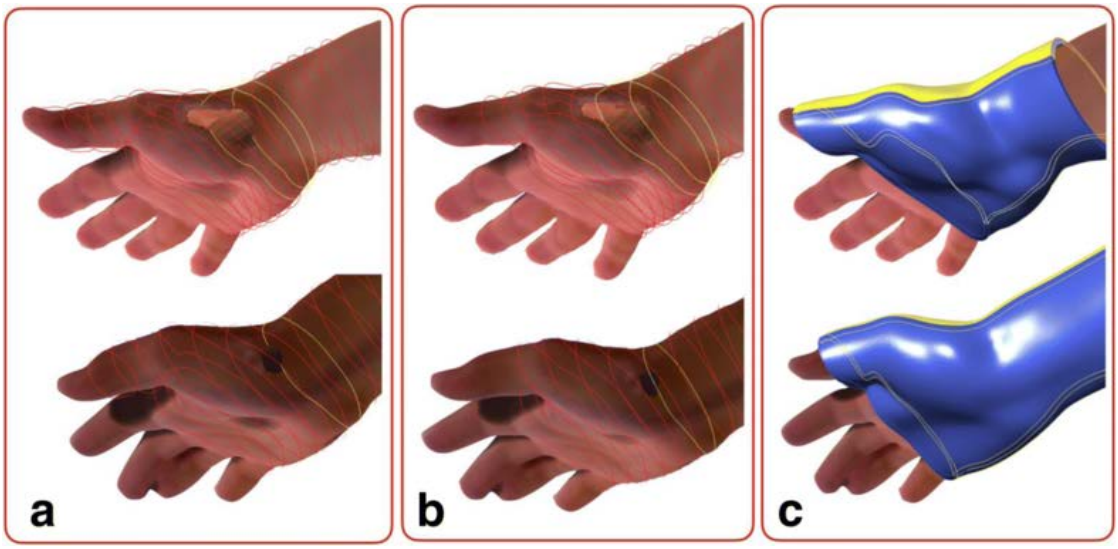


Fig. 7.2 Result obtained upon fixing lost meshes in samples A and E—(a) Holes in samples A and E; (b) Regenerated closed cross-sections; and (c) Complete shells

7.2.2 Prototype fabrication

Here, we calculated the required printing time for the six samples. After exporting the STL files, the Simplify 3D 4.0 (Simplify 3D) [94] slicer software was applied to calculate the printing time with identical settings. The splints were all printed at a standing angle, as depicted in Fig. 7.3, for conserving support material and saving printing time.

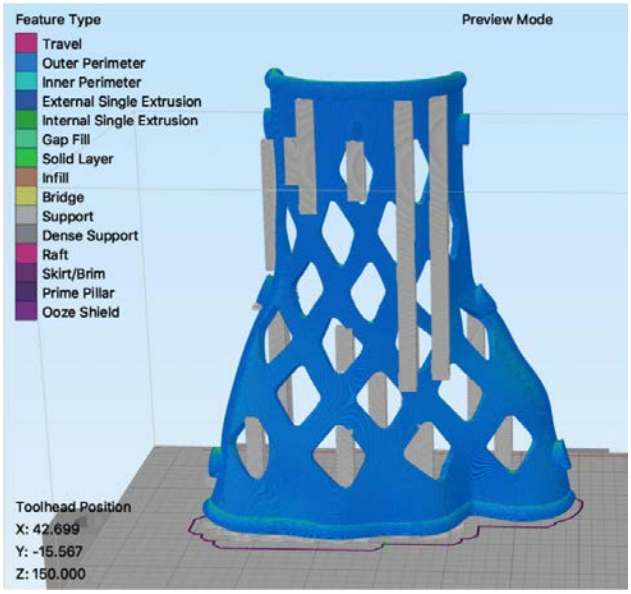


Fig. 7.3 Printing placement in slicer software and printed prototype.

Although the system divided the splint into parts with equal volumes, there were few errors in the printing of each part due to differences in the shape, lattice area, and consumed supports. The build time, splint weight, and height statistics of all the splint parts are listed in Table 7.2; the longest printing duration for the splint part indicates the time, when the splint can be ready for the patient. The ready time was approximately 3 h to less than 6 h, depending on the splint height and the total splint weight ranged between 79–221 g.

A commercial fused deposition modeling 3D printer, QIDI Tech1 (QIDI Technology), and PLA material were used to print the splints. The generated splint did not need further finishing, after the supports were removed by hand in a few minutes. One of the printed splints, shown in Fig. 7.4, was used to test the wearability and comfort in Chapter 8.

Table. 7.2 Fabrication-data statistics. It includes the printing time, weight, and height of all splint components calculated using slicer software

Sample	part no	2-parts splint			3-parts splint		
		build time (h:m)	weight (g)	height (mm)	build time (h : m)	weight (g)	height (mm)
A	1	2:42	44	129	4:28	64	259
	2	2:59	53	129	4:18	57	256
	3				4:35	73	261
total weight			97			194	
B	1	2:20	33	130	3:26	46	205
	2	2:22	36	131	3:16	37	206
	3				3:29	47	209
total weight			69			120	
C	1	2:42	41	158	3:55	47	241
	2	2:49	43	159	3:44	45	235
	3				3:52	43	245
total weight			84			135	
D	1	2:10	30	128	4:27	54	275
	2	2:14	32	128	4:31	53	281
	3				4:34	56	277
total weight			62			163	
E	1	3:38	58	178	4:12	52	257
	2	3:36	62	177	4:13	51	255
	3				4:10	56	257
total weight			120			159	

Fig. 7.4 Printed splint prototypes

Swelling acclimation and comfort

Overcoming inflammations and swellings that occur over the course of fracture treatments is a common issue that must be accounted for during splint design, as prescribed by Fitch [29,69,70]. Splints designed using the proposed system are rigid and fastened by screws; hence, by removing a set of screws along one of the gaps, the splint can be rendered flexible to accommodate limb swelling, as depicted in Fig. 7.5(a and b). Two Velcro straps were employed for fastening the splint and adjusting its fit (Fig. 7.5 (c)) [29]; strap rings could be generated by the system—in a manner similar to placement-screw seats placed along gaps—for fixing Velcro straps (Fig. 7.5 (d)). However, long-term usage and limb swelling may cause tissue herniation into the lattice structure. To preventing such occurrences, holes within the lattice structure must be shrunk by adjusting relevant parameters or hole distribution in the concerned area must be altered. Besides, use of a flexible gauze to encapsulate the affected limb, prior to wearing the splint, must be considered as part of the immobilization treatment. Through use of the above methods, user comfort can be ensured during fitting and rounded splint edges can be created to effectively buffer the friction between the splint and limb skin.

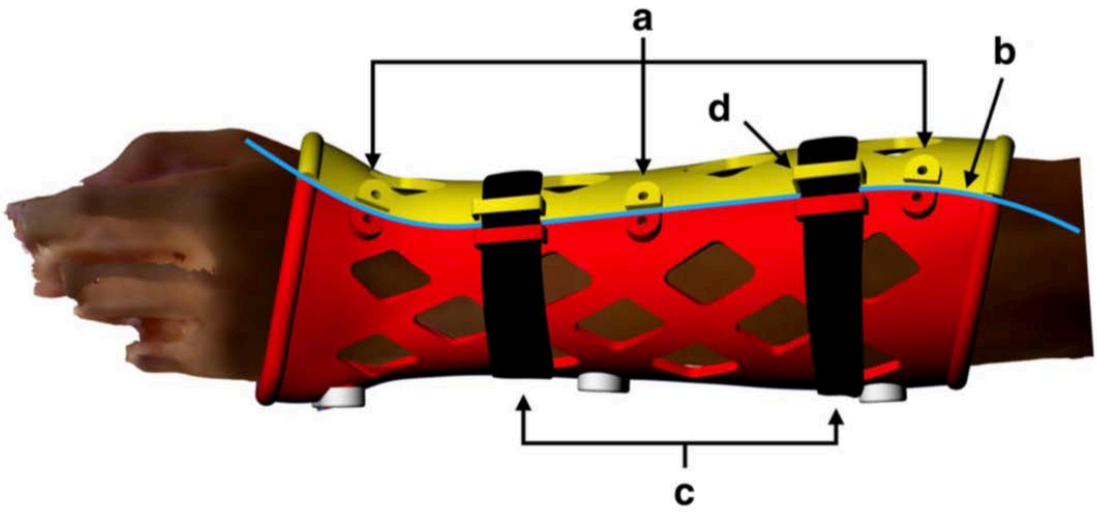


Fig.7.5. Solution to swelling accommodation—**(a)** Screw remove from gap; **(b)** Gap opening; **(c)** Velcro straps; and **(d)** Strap rings

7.3 Experiment 2

7.3.1 Stability and efficiency of generating printable models

We applied the semi-automatic modeling process on five face samples to test the stability of respirator generation, and each customization design was completed in 2 - 4 minutes successfully (Fig. 7.6). The Curve X and position of filter assembly are depend on the features of face samples. The adjustment of Curve X, Pt 1 and Pt 2 are free to be adjusted as many times in whole process. The model updating only takes 2-4 seconds after every adjustment, and can be ignored to record.

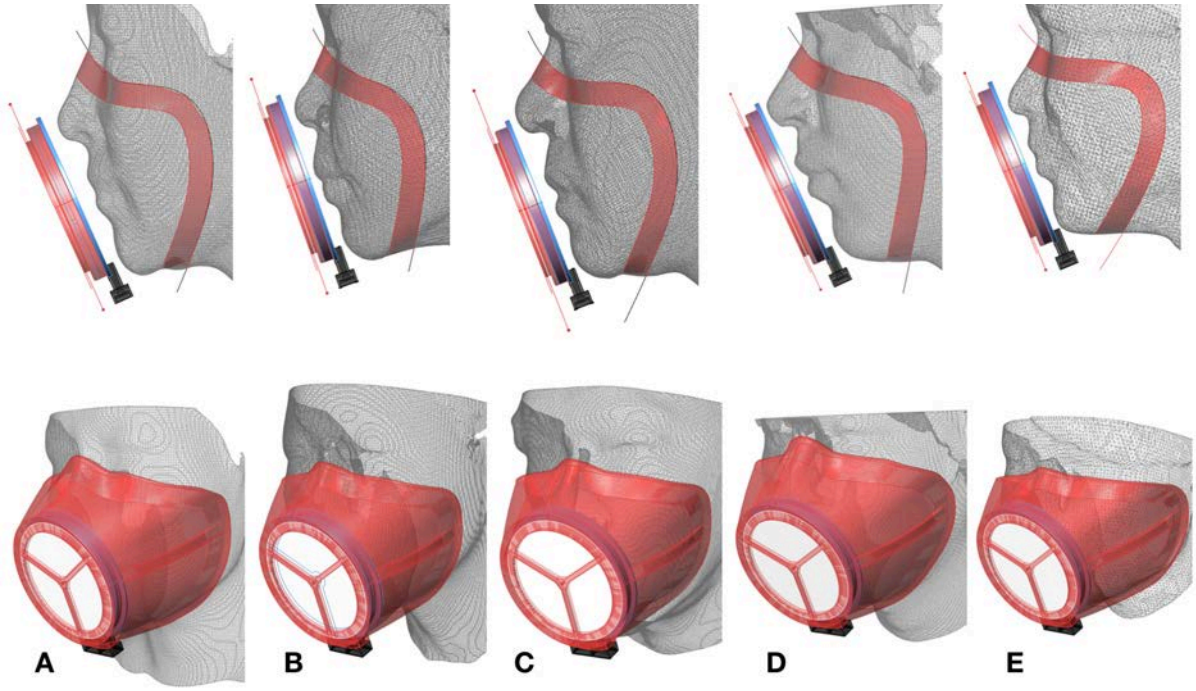


Fig. 7.6. Design results on five samples.

7.3.2 Prototype fabrication

After exporting the STL files, the Simplify 3D 4.0 (Simplify 3D) slicer software was applied to export printing files with identical settings. The respirators were all printed at a standing angle, as depicted in Fig.7.7, for conserving support material and saving printing time. Several settings are suggested in the printing for respirator performance. The layer from the height 0 to 3.41 mm, the front end of respirator, is set as 20% filling percentage for better strength and hold the filter firmly (Fig. 7.7a), then after 3.41 mm, the filling percentage is set as 5 - 7% for better softness and flexibility (Fig. 7.7b). From the start layer of covering surface to the end, the printing quality can be set highest to

Fig. 7.7. Printed respirator of Sample C.

decrease the layer notch for good comfortability when wearing. Though applying low filling percentage, the weights of 5 respirators ranged between 60–80 g. Then, Qidi Tech 1, a commercial fused deposition modeling 3D printer (QIDI Technology) and Fabrial-R material (JSR, Japan) were used to print the respirator for Sample C (Fig.7.8). The generated respirator did not need further finishing, after the supports were removed by hand in a few minutes. The printing time takes about 5 h.

Fig. 7.8. Printed respirator of Sample C, and comparison with the design file.

7.3.3 Discussion

This respirator design is limited by available options of filter material and types, the form and size of respirator are depend on the filter shape. Compared the foldable N95 mask, although the flat filter we used makes this respirator looks much bigger visually, but it provides stable base layers and success rate in the printing. Besides, foldable mask usually attaches on wearer's face tightly to avoid air leakage, but it causes moisture and heat build-up when wearing. The customized respirator only contacts the skin around the nose and mouth, and contain enough distance and space inside the mask to keep the skin dry and comfort.

In the face calibration of input stage, the inevitable dissymmetry of human face or slight tilt when scan are frequent problems, ICP may not find a perfect mirror plane to continue the input. For example, the wearer’s both cheeks may have different width from the mirror plane, although the nose and eye are well symmetric. ICP should choose the narrow side to project Curve X and avoid the possibility of air leakage happen on the cheek. Besides, if the wearer has obvious weight change, that might impact the seal tightness of respirator on face, and 3D scan is necessary to be repeated for the wearer.

Chapter 8
Evaluation

8.1 Introduction

In this chapter, I formulated operative training and design exercises for design agents in the two experiments, and they need to learn the basic operation, developing their skills, and troubleshooting and interfacing Rhino and Grasshopper. The training contents are designed to be taught and memorized in 30 minutes. In the design exercises, design agents need to follow the training and complete the customization design in the simulations of real design situation on provided scan samples. From the design agents' performance in the design exercise, we can evaluate and improve the training effect and system performance based on visual results. Finally, the function and performance of the customized product may vary with the customization conditions, so corresponding evaluations for physical product are executed to verify the product quality are secured.

8.2 Experiment 1

8.2.1 Training

Based on the modeling process, workflow and interface of Experiment 1, a training program was formulated to teach clinicians to utilize this parametric model of orthosis design and export a printable model. The training content, includes an introduction to 3D-printed orthosis, an operating tutorial and computer-based practice. Five nursing students in their junior year were invited to undergo this training, and they then completed an orthosis design exercise to evaluate the function of the parametric model and training. The participants had internship experience in the orthopedic department in the hospital and were familiar with manipulating fracture immobilizations. They were capable of operating document software, internet browsers and apps on mobile device in daily life, but did not have any CAD background.

The introduction included demonstrations of the digital models and physical orthosis and explanations of the orthosis design and 3D printing process to the participants. One

of the prototypes was prefabricated for demonstration. The participant could learn how the 3D-printed orthosis was assembled, produced and functioned for patient rehabilitation. Then, the computer-based tutorial was provided one-on-one, and the necessary operational knowledge of the Rhino and Grasshopper programs was summarized as the following points:

- Basic viewport navigation in Rhino: Please refer to Section 5.3.1.
- Draw and fix the landmark: The drawing is operated by setting 2 lines in the top view, and accomplished atomically when the shape is closed. If the line does not match the expected immobilization area, the operator can redraw it to replace a previous one.
- Select Rhino object and assign to Grasshopper: Please refer to Section 5.3.1.
- Control data flow in Grasshopper: Clicking the toggles can change its output (True/ False) and then send out the geometric data to next modeling process. The orthosis model will be updated by clicking toggles in order, and most toggles do not work if the previous toggle produced a false value.
- Solve program error or software crash: Sometimes, because the immobilization area overlapped on the limb model's edge or a hole, the parametric model may generate a distorted surface, separate objects or have no response when attempting to update a model, even causing Rhino to crash. Correcting the immobilization area from the edge or hole can avoid these problems.

5 limb models were used during this tutorial. The tutor used 2 of these to demonstrate the process, and participants followed the same steps. The participants could ask the tutor to repeat the process until they had memorized the whole procedure and its underlying logic. Then, another 3 limb models were provided to participants for practice, and they were asked to design orthoses without the tutor's help. The participants were encouraged to solve the problems that arose during the process by themselves as much as possible, but they could ask the tutor for hints as needed. The total time during the training was recorded after they accomplished the procedure.

8.2.2 Design exercise and visualization

After the training, the participants completed a trial to design orthoses for another 5 limb models on their own. The limb models were saved in different layers of a file, and participants were asked to switch the layers and design the orthoses in order. The working processes on screen were recorded as videos, and visualized by the method of

Section 5.3. After the participants completed the exercise, an interview was held. If the participant's intention for any event was not obvious enough to determine a label, e.g., they were confused or forgot a step, the tutor should confirm what occurred with the participant in the interview. However, the main purpose of the interview was to collect the participants' opinions regarding the parametric model and training program based on their experience.

Then, the participants completed an orthosis design exercise, and their recorded videos of the design process were labeled A to E and visualized using color labels as in the bar charts of Fig. 8.1. We differentiated each orthosis design period on the timeline from the other designs by black lines, and marked the precise time points when they finished

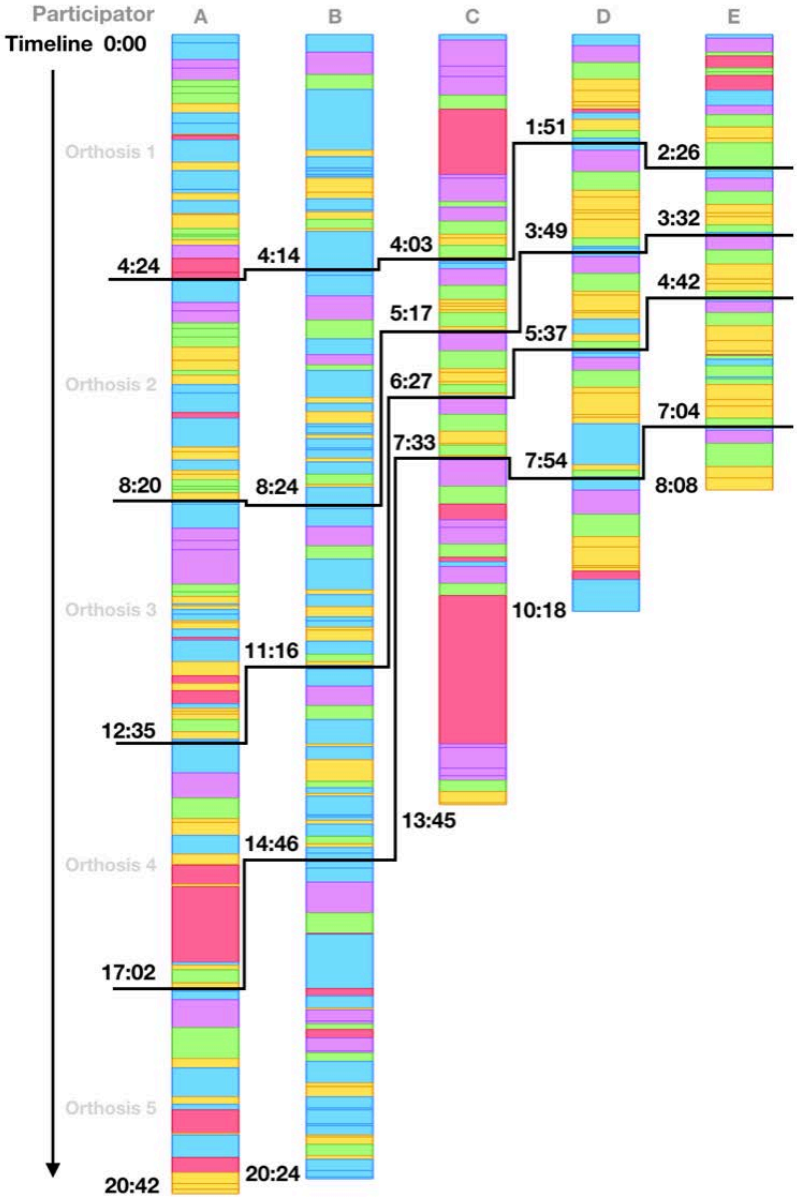


Fig.8.1 Labeled bar chart of 5 participants' video records.

each design, i.e., participant A finished the first orthosis at 4 mins and 24 secs, whereas participant B spent 4 mins 14 s. From the video visualization, the participants finished the 5 designs in a period ranging from 8 to 21 mins, and each design took between 1 and 7 mins. Compared to manual modeling, the time required for the parametric model has been reduced dramatically. From the interview, most participants gave positive evaluations of this digital tool and training, and more practice and verification with a printed model could help them avoid mistakes and improve their drawing skills to define the immobilization area.

In the video, we marked the following program error and participant mistakes with red labels.

- Wrong operation: The participant took unnecessary steps or missed an operation, such as moving the wrong objects or utilizing extra clicks, although these negative faults did not impact the process critically. We added these faults as frequently asked questions in the updated tutorial, which allowed other beginners to avoid repeating them.
- Input failure or invalid model generated: Usually these program errors occurred after the input setting or during the modeling calculation. The parametric model did not update the orthosis model after the toggles were activated, e.g., the thickening or engraving function failed, or sometimes it generated a valid model that had a distorted surface or separate objects on the shell. These errors indicated defects in the Grasshopper program or limb model.
- Software crash: If the participant wasn't aware of the boundary or lost the mesh on the limb model, they may have set immobilization areas overlapping the model's edge or a hole. The model process may generate incomplete cross-sections or geometries and cause Rhino to crash because they disturbed the data tree and initiated massive numbers of calculations instantly in Grasshopper. The participant needed to restart the software and modify the immobilization area again.

The frequency of red label marking was enumerated from 25 orthosis designs in Table 8.1. Only 2 crashes occurred, and the participants learned to modify the immobilization area to solved these issues by themselves. Very high fault times occurred in participant A's record, although most faults were minimal, such as moving the wrong object or performing extra clicks absentmindedly. The faults did not obstruct the participant significantly, and the parametric model worked perfectly. igns by black lines, and

marked the precise time points when they finished each design, i.e., participant A finished the first orthosis at 4 mins and 24 secs, whereas participant B spent 4 m 14 s. From the video visualization, the participants finished the 5 designs in a period ranging from 8 to 21 mins, and each design took between 1 and 7 mins. Compared to manual modeling, the time required for the parametric model has been reduced dramatically. From the interview, most participants gave positive evaluations of this digital tool and training, and more practice and verification with a printed model could help them avoid mistakes and improve their drawing skills to define the immobilization area.

Table 8.1 Accumulation of red labels

	1. Operation fault	2. Input failure or invalid generation	3. Software crash
A	11	0	0
B	0	2	0
C	1	2	1
D	1	1	0
E	1	1	1

The frequency of red label marking was enumerated from 25 orthosis designs in Table 8.1. Only 2 crashes occurred, and the participants learned to modify the immobilization area to solved these issues by themselves. Very high fault times occurred in participant A's record, although most faults were minimal, such as moving the wrong object or performing extra clicks absentmindedly. The faults did not obstruct the participant significantly, and the parametric model worked perfectly.

Additionally, several interesting discoveries from the video provided useful feedback regarding the participant's behavior. We extracted the total time expended from the event labels as well as their percentages relative to the whole process for each participant, and presented them as a pie chart in Fig. 8.2.

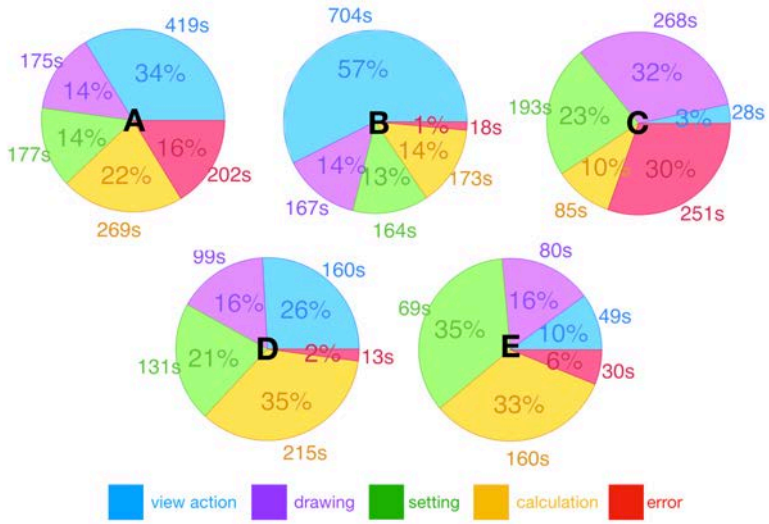


Fig. 8.2 Pie chart of event percentages and spent seconds.

In the analyzed results of participant B, we found the participant made almost no mistakes in the operation during the exercise and no crash occurred. The blue labels represented 57% of her process; the observations were confirmed from the video, with a high blue percentage indicating she spent most of the time checking the limb model's appearance and edges in the viewport and deciding how to draw the immobilization area. Her drawing avoided the edges and holes of the model skillfully, and this was the factor that allows the program to generate the orthosis model successfully. Long seconds of drawing were found in participant C's process, and repeated drawing occurred in the video when the immobilization area did not cover the expected surface. Developing another input drawing method could solve this challenge, but this is usually limited by the available drawing command and necessary geometric logic to generate cross-sections. Additionally, long periods of waiting for software calculations also appeared in participant A and D's videos, and long calculations usually occurred in the engraving pattern, especially when it worked on a deformed surface around the wrist. A hexagon or diamond array would be more stable than the Voronoi diagram for the engraving task. The random points of the Voronoi algorithm do marginally increase the risk of generating tiny holes and failing the projection on the surface.

8.2.3 FEA and fitness investigation

Finite element analysis

A finite element analysis (FEA)-based static stress simulation was performed to test the engineering strength of generated splint designs against predictable forces. Two- and three-part splint designs based on the previously mentioned limb sample were imported

into Fusion 360 (Autodesk) to perform an independent simulation. Acrylonitrile butadiene styrene (ABS) was used as the material to define material properties in the simulation setup with Young's Modulus (E) and Poisson Ratio (v) values of the order of 2,240 MPa and 0.38, respectively [66, 68]. Splint parts were assembled using screws to resemble a patient's limb in a state of immobilization to facilitate their import into the simulation as a single object (Fig.8.3(a)). The splint model was simplified to facilitate simulation calculations by removing round edges and screw seats. The structural constraint was set with the proximal edge marked as the fixed base. The thickness and lattice structure density of splint were varied in accordance with the splint size in the modeling program. The 2-part splint was generated with a thickness measuring 3.2 mm and a 6 × 9 diamond array on the structure of each part. Likewise, the 3-part splint measured 4-mm thick with a 9 × 5 diamond array on each part structure. A structural load of 30 N was applied on the distal edge of the splint and lattice-structure area along three directions separately to simulate possible hits and stresses that may unintentionally occur during the recovery period. Results obtained this simulation along with maximum von Mises stress values and displacements are depicted in Fig. 8.3(b,) demonstrating sufficient strength of the proposed splint designs.

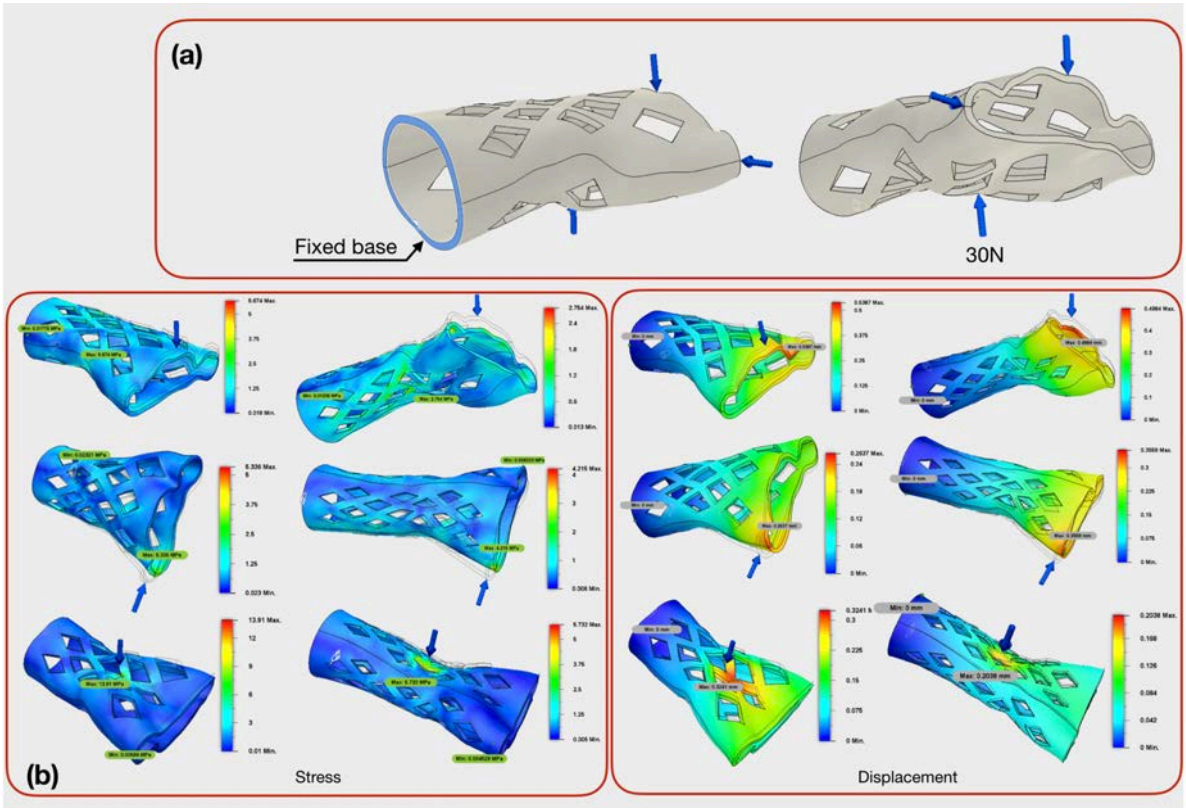
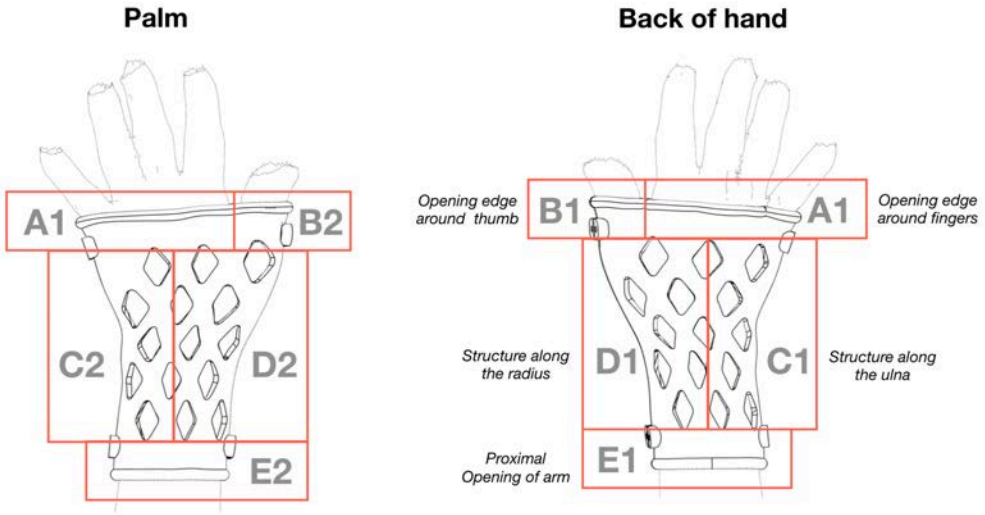


Fig. 8.3 FEA test and result. (a) Structural constraints and load of simulation setting; (b) FEA result, von Mises stress value, and displacement under applied splint loading. The maximal Von Mises stress value is 13.91 MPa and maximal displacement is 0.53 mm, both values occured on the 2-parts splint.

Fitness investigation

A 3-hour wearing experiment was performed on health volunteers within an enclosed environment, and a 3-level-scaled questionnaire was designed to assess their experience of wearing splints designed using the proposed system. The purpose of this experiment was to determine possible faults in the splint design, thereby facilitating preparations for performing further studies involving more wearers, longer durations, and larger immobilization regions. Five performance indicators were considered in this investigation, including wearing fitness, immobilization strength, sweating, skin itchiness, and inflammation, and a set of wrist figures were attached in the questionnaire for the wearer to mark specific positions of the above-mentioned discomforts, including locations of pressure sore, splint-structure cracking, sweating, and inflammation (Fig. 8.4).



Please feedback your wearing experience by checking following questions and fill corresponding position code(s) (A1~E2) of discomfort according the figures. If it is positive evaluation, please skip the position code.

- Wearing fitness: loose or pressure sore appear on the splint. □heavy □slight □ comfort. Position code: ____
- Immobilization strength: Splint structure appears □ break or crack □ bend □strong. Position code: ____
- Sweating: □critical □slight □ comfort. position code: ____
- Skin itchiness: □critical □slight □ comfort. position code: ____
- Inflammation: □critical □slight □ comfort. position code: ____

Fig. 8.4 Splint fit questionnaire.

Five 2-part wrist splints were tested by health volunteers involved in splint-fit investigation. The wearers did not demonstrate any actual fracture symptoms; therefore, no offset operation for swelling adaption was performed during the design of these splint models. Results of the questionnaire answered by wearers are listed in Table 8.2, and no critical discomfort was reported. The splint features were customized based on 3D scan data with a view to provide comfortable fit to wearers' limbs. Furthermore, the lattice structure that covered majority of the limb area was observed to improve ventilation, thereby preventing the wearers from facing issues related to sweating.

Minor pressure sores and skin itchiness around position C1, the styloid process of ulna were, however, reported in three cases. These were observed to be caused by friction between the skin and hole edges within the lattice structure. To prevent hole edges of lattice structures from contacting the skin near bony regions, the lattice pattern must be made adjustable during the modeling process.

Table. 8.2. Statistics result of marked times on each splint area based on the marked positions on questionnaires. The discomfort feedback of “Critical” is marked as ●, and “Slight” is marked as ○. Feedback of “Comfort” remained as blank. No critical discomfort was reported.

	Indicators				
Position Code	Fitness	Structural Strength	Sweating	Skin itchiness	Inflammation
A1					
B1				O	
C1	O			OO	
D1					
E1					
A2					
B2					
C2			O		
D2		O			
E2				O	

8.3 Experiment 2

8.3.1 Training

Based on the digital design tool of Experiment 2, a training program was formulated to teach ICP to utilize this parametric model of design a printable model. The training content, includes an introduction to 3D-printed respirator, an operating tutorial and computer-based practice.

3 nursing students between junior to senior year were invited to undergo this training as the participants, then they take the design exercise to evaluate the function of the parametric model and training. The participants have accepted basic training in the hospital, sterilization knowledge and 3D scanning experience, and also interested in the personalized protective device. The design process of respirator can be completed once the input conditions are fulfilled. The curve and points are adjustable to interact the modeling result in realtime. The training content includes:

- Basic viewport navigation and layer panel control in Rhino.
- Drawing curve and setting points: In this experiment, the participant can draw a curve by Interpolate Curve command from the side view to define the contact area of respirator. If the curve does not cover the expected area around the nose and mouth of reference head model, the operator can redraw it to replace a previous one. Then the participant can set two points to define the position of filter structure, and the modeling sequence will connect the structure and contact area by surfaces and complete the mask model.
- Assign geometries into Grasshopper: The operator needs to know how to assign the face model, curve and points into Grasshopper, and clean all settings when continue to the next face model.
- Solve program error or software crash: Because the scanned face area required for the respirator design is much smaller than the splint design, it is easier to get completed face models in this experiment. Almost no program failure occurs in the modeling generation. However, the two points that decide the filter position should be in a reasonable area near the line between the nose tip and lowest point of jaw, if the two points are set to far away, the modeling program will not generate mask body. The participant should mind the possibility.

5 face models were used in this training. The tutor explained the modeling principles and demonstrated the design steps on a face model, and participants followed the steps repeatedly until they can memorize it.

8.3.2 Design exercise and performance visualization

After the training, the participants are asked to design another 5 respirators by themselves, and their work process on the screen were recorded and visualized as Fig. 8.5. Participants were labeled as A to C, and they completed the exercises in a period from 9 to 13 mins. Their bar charts are divided by black lines to differentiate each design, and they took between 2 to 3 mins. Participant C is more skilled on how the

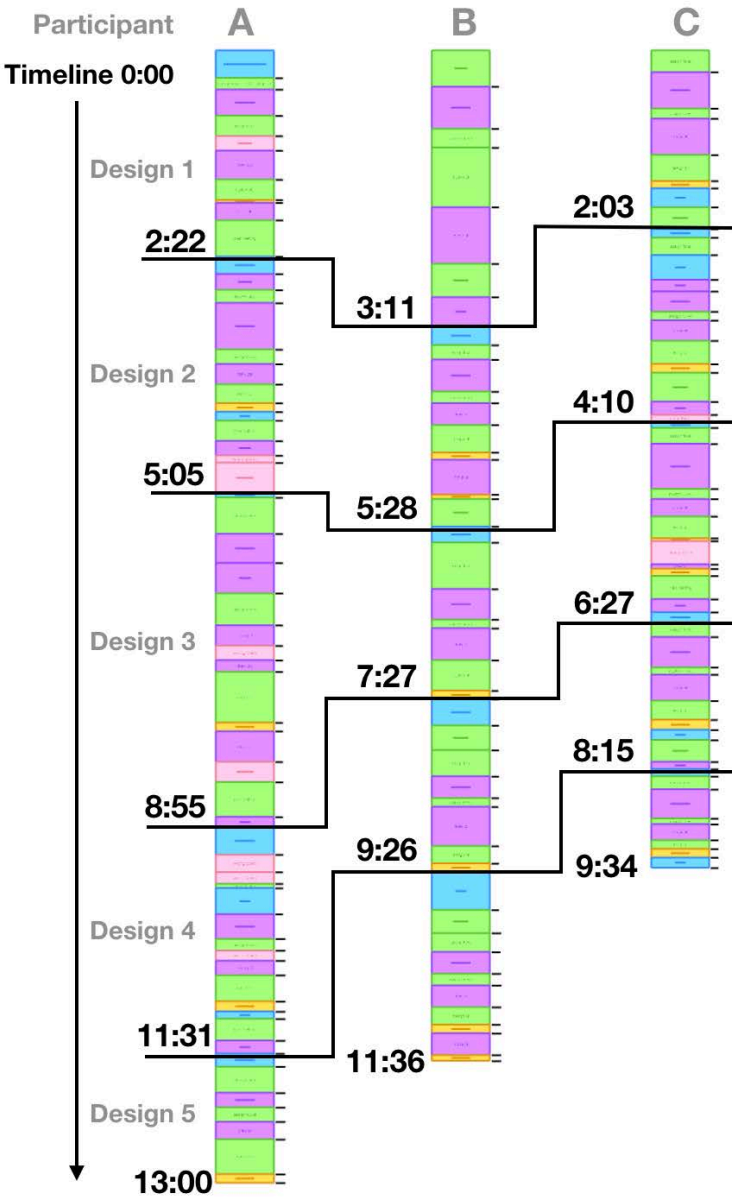


Fig. 8.5 Labeled bar chart of 3 participants' video records

interface is switched and saved much time on the operation. In their bar charts, purple bars present the time they spent on drawing and setting points, and green bars present the part they worked on Grasshopper setting. These two color occupy most period and similar percentages in the exercise as the pie chart in Fig. 8.6. The red parts present the tool did not response to their input in few cases, because the points' positions were not set into the ideal area. Generally, all participants can learn the design tool in the short training quickly and have enough performances.

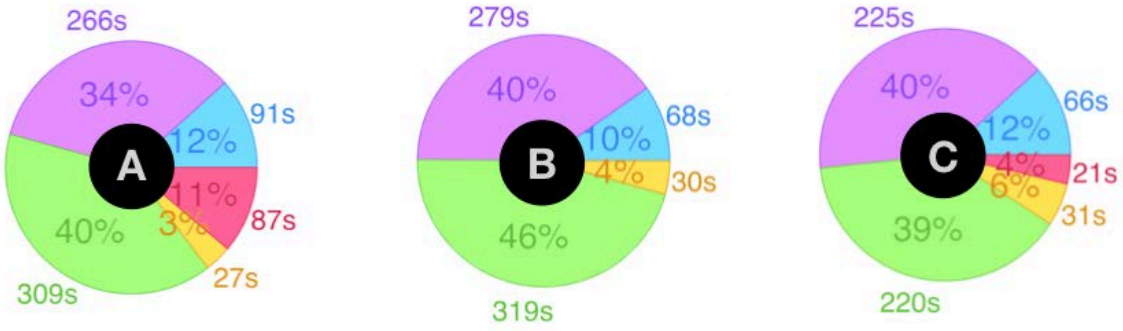


Fig. 8.6 Pie chart of event percentages and seconds spent in the participants' videos.

8.3.3 Fit test

As mentioned in Section 6.2, the hospital employees are required to do the annual fit test to ensure the respirator fit the wearer's face, and QNFT and QLFT are the mainstream methods. The advantages of two methods have been compared in many studies [95-97], and QNFT requires expensive instrument and trained personnel. The high prices and poor accessibility are common excuses for not carry out fit test [98-99] , so I select QLFT method to evaluate the devices generated in the experiment. There are several QLFT kit available on the market, such as 3M FT-10 Test Kit [100] or TSI Q Fit Kit [101]. Although these kits are relatively cheaper than QNFT equipments, but they are still costly. According to a literature showed that inexpensive pneumatic medical nebulizers could be substitutions for the aerosol generators of those kits [95], I designed a set of 3D printed parts and low-cost DIY head hood to work with the nebulizer (B-Best) verified in the reference and 3M sensitivity solution as shown in Fig. 8.7 in the evaluation [102]. These 3D printed parts' files are available on Thingiverse platform for who are interested to do QLFT in a low-cost kit.

Fig. 8.7. **a**. 3D printed parts, nebulizer and sweet testing sensitivity solution of 3M FT-10 kit **b**. DIY head hood. **c**. Assembled parts. **d**. Simulating fit test. **e**. Assembled parts.

3 volunteers attended the evaluation, and they accepted facial 3D scanning for customizing their personalized respirators. After the mask completed, they uses the test kit and followed the QLFT protocols. In the test, the tester used the nebulizer to inject solution smoke as required concentration into the head hood, then the participants followed the instruction to do the action. From the result, no external air leak into the mask body is reported by participants.

8.3.4 Sterilization

Because the printed respirator is reusable for two or three months, the daily sterilization after using is necessary. Two frequent sterilization methods that suggested for the reused objects in the hospital are applied, include boiling and Hypochlorous acid solution soaking as Fig.8.8, and the respirators did not appear deformed, deterioration or discoloration in two weeks. In the bacterial growing detection, the agar medium is used

to collect the inside surface of respirators carefully, and less than 10 bacterial spots are found in the result after 48 hours of bacteria growing (Fig. 8.9).

Fig. 8.8. Prototypes passed the material test in the sterilizations.

Fig. 8.9. Bacteria test result. **a.** agar medium. **b**. collecting bacterials on mask internal surface **c.** Developed result after developing in environmental temperature of 37degree for 48 hours.

Chapter 9
Conclusion

9.1 Introduction

In this chapter, I present the contributions of this research and address their future effect inside/outside of the hospital and with the involved medical professionals. Some findings observed from the experiments are addressed from the viewpoints of clinicians, medical staff, and hospital administrator in Section 9.3. Discovered and predicable limitations on medical technology and corresponding study directions are discussed in Section 9.4. Finally, I explain how the technical evolution affects the medical professionals' relationships by Actor-Network Theory and share my experience in applying the research result to open source in Section 9.5.

9.2 Contribution

In the two experiments of this research, the participants applied the specialized design tool developed for fracture splint and filter respirator and completed prototypes on different anatomical models; these designs were materialized and passed the related evaluations. These results prove several points in the hypothesis as Fig. 9.1:

1) Collaboration: Based on the proposed method, medical engineer can study knowledge and requirement about medical product from clinician, and plan the product, design tool and training together. Then through a well-planned modeling sequence, interface design and quick training, clinicians can learn and apply the basic capability of operating the digital design tool.
2) New tool: Through the programmable modeling tool, engineers can enable clinicians to operate a rapid customization process for device design in few minutes; thus, this tool can reduce the consumed time of design stage and substantially save on professional costs. Its efficiency allows clinicians to attempt different design solutions and refine them in real time.
3) New role: In the process, clinician and medical engineer switch to the new roles. Medical engineer becomes the tool developer from the tool user of commercial

CAD software. Clinicians become the design agent who customizes product for patient directly, and they can complete the device design independently without any technical support to output the device file and achieve fabrication.

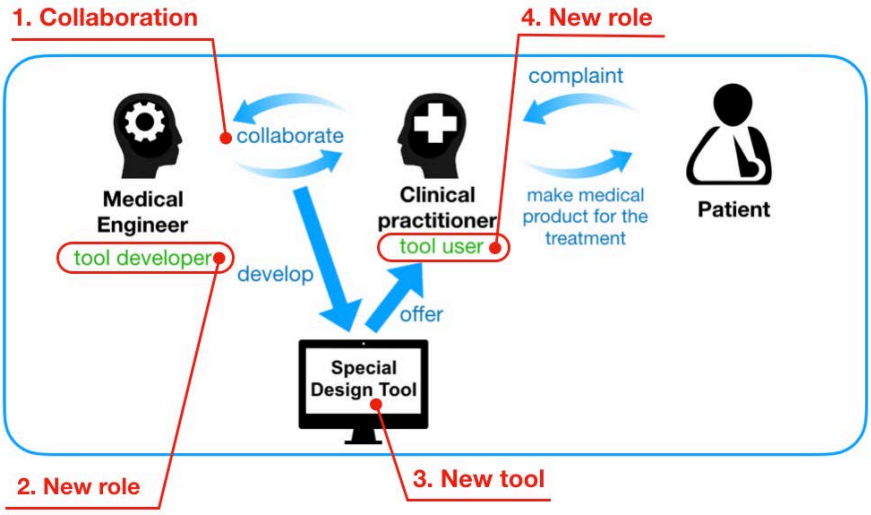


Fig. 9.1. Research contributions that response to the hypothesis map.

A followable method for other healthcare scenes

In the healthcare fields, digital fabrication technology is not only affecting the medical devices applied in the hospital setting but also includes other medical requirements that occur in home care or nursing facilities. The healthcare practitioner that work in these areas are eager to obtain the advantages offered by digital fabrication and to overcome the digitalized obstacles as well.

Although this dissertation focuses on medical devices of clinical treatment and regulated by the FDA, digital fabrication has attracted widespread public attention in long-term care categories and with applications for low-risk nursing purposes. These scenes or facilities usually lack hardware resources and financial support or are located at remote districts; therefore, their distinctive demands on medical and assistive devices are not profitable enough to attract the manufacturers to invest resources into producing their expected devices. Before the advent of digital fabrication technology, DIY was the frequent solution to modify objects (Fig. 9.2), but it is limited by local material and available tools.

Fig. 9.2. Modified tableware and foot rehabilitation device. These appliance are made by the caretakers of New Comfort Nursing Home facility in Taiwan for patients of cerebral palsy or degenerative disease.

Therefore, for many therapists, long-term caregivers, and these nursing facilities, digital fabrication technology brings them the opportunity to solve various daily needs of their patients by utilizing a low-cost 3-D printer and making various assistive tools as Fig. 9.3. On social community platforms, more and more similar groups exchange information and experience with making device prototypes, such as “Fab OT/Fab Lab Shinagawa” in Japan or “OT x maker” in Taiwan.

The framework and thinking proposed in this research provide a followable method for healthcare practitioners to collaborate with designers and engineers. Through the codesign of the digital tool development, the healthcare practitioners can obtain appropriate tools and distribute design and fabrication for their works and patients.

Fig. 9.3. Two sets of assertive devices. These designs are developed in Tinker CAD software and made by Sonoko Hayashi of FabLab Shinagawa and shared in the name of “FabOT” on their Facebook community, 2018.

9.3 Observation

From the experimental results, development process, and contacts with participants, many issues and phenomenon have been observed. I listed these findings below, as they will be helpful for clinicians and hospital administrators when developing similar design tools and operations for the customization of medical devices in the future.

For clinicians

In the experiments, many participants showed a significant gap when comparing their performance in terms of time efficiency and failure rate, although they all are equally inexperienced with CAD. Although relatively poor performance does not affect the participant's ability to complete the training and exercise, some findings can help engineers to plan the training and avoid similar problems.

With the performance of some excellent participants, their proficiency with software detailed feedbacks, such as being able to predict the window switch and having an awareness of current working windows, saved much time and reduced wrong operation for them. In addition, most clinicians understand how to use the digital interface to check and interpret medical images, but for building geometries on this interface, they still need more experience. For example, in the case of customizing the respirator, the design manual requires ICP to project a curve from the side direction or X axis on the face model to decide the covering area of respirator, but sometimes, the ICP could not identify the facial muscles on the model clearly in the beginning trials to make an appropriate curve. A poor design may cause the air leak into the respirator when the user was speaking in the QLFT, but such issues can be fixed by showing good and bad designs to the ICP and explaining how the design results were generated from the different curves.

For the hospital administrator

In the collaborative framework, the medical engineer plays an important role in the technical construction, and their availability is the prerequisite condition for the medical units interested in customizing medical device. The growing trend of introducing digital fabrication equipment into a medical environment is conductive to the employment of medical engineers, because they are in an ideal position to maintain and operate these types of manufacturing equipment.

Design tool development is suggested to be preceded by internal employees who share common environment and efficient communication; however, due to remote locations or the limited resources of some small clinics or hospitals, medical engineers are not

always available. These small-scale units have difficulty developing a design tool and product on their own, and external sources can be considered as options. These medical units can send their clinicians to participate in a collaborative development organized by multiple hospitals or seek the authorization to use a developed design tool and related training support.

This research recommends a vertical integration of medical device design and manufacturing by the hospital staff, and in addition to the human resource of medical engineer, the cost of manufacturing equipment and operation should be considered. The price of 3-D printing equipment can be significantly different according to the technical type. SLS or SLA printing usually requires expensive equipment and longer production period, but offers better precision and surface finish, and in this research, FFF/FDM technology is the main technology applied in the experiments, and it is less costly for equipment, material and training and has better manufacturing efficiency. Due to the economical efficiency, FFF/FDM equipment own a wider user group than industrial printing machines to accumulate more feedback, and the printing quality got improved obviously in the recent years. From the experiments and product type, FFF/FDM printer offers enough feasibility for the medical products. The application of FFF/FDM technology is the key factor to reduce the cost for hospital administration, and a small/ medium hospital can afford multiple FFF/FDM printers and plenty of material for an internal manufacturing lab. In the case of upper limb splinting, each splint weighs approximately 70-200 g, and a standard roll of filament can be used on five sets of splints. Normally, the cost of PLA or ABS filament is approximately 2000-3000 JPY, and a roll of medial grade Nylon filament usually costs 7000 JPY. Actual material cost of a forearm splint may only require 1200 JPY, and it does not include the cost of the equipment, space and administration.

9.4 Limitations and future works

In this research, the feasibility of operating a design tool and generating device designs by clinicians and generating customized devices have received initial approval. Some limitations of this method are discussed in this section, and additional data are expected to be collected in future research.

Fit tolerance and anthropometric study

The customization of a medical device is mainly based on the static anatomical model captured by 3-D scanning, but real body skin is flexible and changeable, with internal muscle and bone. Possibly, the customized device does not achieve the necessary tight fit on the wearer’s body in its first prototype and will require further adjustment to fix it.

Additionally, the wearer's age, sex, and body fat may affect the skin or limb differently, Skinny and obese people may have very different experience on waring the products designed with the same fit tolerance. Precisely controlling the right tolerance between the device and anatomy to maintain comfort and a tight fit regularly requires experience and wearer feedback.

Therefore, further scanned samples of anatomical models should be collected widely for anthropometric study, especially for extreme cases, such as for children or male adult. These samples can be applied in the corresponding design tool to generate printable models for related evaluation, and the result can improve the parameters and algorithm of the design tool or offer referable tolerance parameters for other clinicians who are beginners to the tool.

Limitation of static scanned model

For the design requirement of orthotic devices that correct patient neuromuscular and skeletal systems, such as a brace for Scoliosis or Hallux Valgus, the device design method proposed in this research is limited to the existing features of the wearer's anatomy and is unable to correct that anatomy to its original shape. Some specialized CAD software has been developed for this purpose, such as ScoliCAD for Scoliosis brace design. A similar adjustment modeling function can be developed in the same modeling environment that is used herein. However, that would require a set of continuous medical images, such as applying CT 4D Scan, to capture the suitable anatomical model or to generate an adjustable model from the gradual transformation of the image.

Low scanning quality

Considered as economical, efficient, and available, 3-D scanning is still the main solution for current anatomical model acquisition, but its unstable quality is still the factor that critically affects the feasibility. The completeness and authenticity of the scanned models' quality may decrease significantly due to a light-insufficient environment, scanned object's uncontrollable movement, or an operator's unstable hold. Although the DIY scanner mount with additional lighting is highly recommended to solve the above issues, assertive hardware cannot be popularized in a short time. Low scanning quality will be a frequent issue in this application, as well as in the near future, if hardware notwithstanding, a software solution is developed to fix the scanned flaws and is more accessible. In Experiment 1, the holes on the different palm models are fixed by the modeling program, and the hole sizes are identified as a reference. Collecting more scanned flawed cases is necessary for developing a corresponding method to fix the problem, and flaw tolerance is practical information for other clinicians to decide the necessity of repeating a scan.

Future challenges with complex device design

In the experiments, the input, operation, and interface are simplified as much as possible to help clinicians master the design tool quickly, and these strategies received positive results. However, along with the emergence of expected requirements for using a complex device and adjusting the device's design, the interface and operation process will become more complex and challenge these strategies. The medical engineer should consider the possibility when planning the design tool. In addition, currently, the computation of these device generations is minimized into a few minutes and can be completed on a laptop computer. A more complicated design tool is suggested to be rewritten in other text-based scripting languages if a professional programmer is available because the text programming language has better efficiency than visual programing language (VPL).

Digital landmark for advanced splint designs

In this dissertation, the design tool was developed collaboratively by the medical engineer and clinician to overcome the issues of time consumption and a requirement of CAD knowledge in the digital design stage of the medical device. Furthermore, the generated device will not only aim to replace a traditional device but will also solve further medical demands that cannot be met with traditional devices.

For example, in the case of the fracture splint, its basic principle is to apply rigid material to fix the affected limb. In addition to the fixing function, clinicians cannot limit rotary or twisting movements of specific joints precisely through the traditional splints to prevent patient's excessive motion. For example, in the immobilization of the distal radius fracture, the splint cannot avoid the forearm twisting motion that causes unexpected pain.

The scanned model and modeling program provide the possibilities to solve the requirement through the digital approach; the digital design advantage can help clinicians design the necessary mechanism automatically, as shown in Fig 9.4, which illustrates the generation of a structure that limits the twisting motion when designing the splint. By defining a centric curve on the arm's scanned model and setting two points near the elbow, as shown in Fig. 9.4(a), the design tool can produce a two-part splint (Fig. 9.4(b,c)) and a structure to fix the two parts and limit the twisting motion of the forearm (Fig. 9.4(d,e,f)).

Although this device design requires further revisions and evaluations, the splint's complex mechanism was generated by defining simple landmarks rapidly without a CAD expert's help. These digital landmark methods only require only simple steps and minimal CAD knowledge for clinicians. Unlike the traditional landmark, which is very

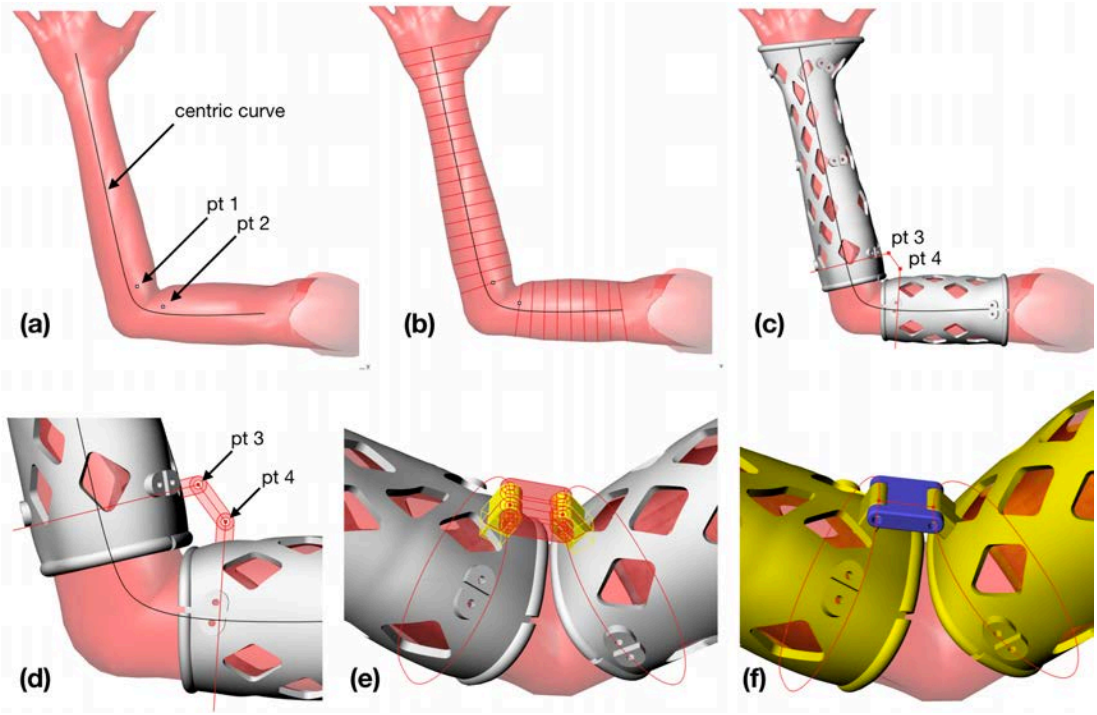


Fig 9.4 Sample of automatic splint structure generation. The structure is developed for limiting twist motion in distal radius fracture. **(a)** Define a centric curve along the effected limb and set two points near elbow to mark the splint ends. **(b)** Red cross-sections are generated and avoid the range between pt1 and pt2. **(c)** A two-part splint set is generated as Experiment 1, and the design tool finds out two referring points for the fixing structure. **(d)** The parametric pattern of structure is generated based on pt3 and pt4. **(e)** The pattern forms the solid structure. **(f)** The printable parts and assembly.

dependent on the clinician's skill and limited by the irreversibility of applying traditional material, the digital landmarking can be more precise for manufacturing, splinting and allowing clinicians to simulate different attempts. Developing advance device designs and landmark methods for other treatment applications will be a rising issue for further research.

Toward to a self-sufficient medical environment

As a predictable trend, the diffusion of digital fabrication technology and hardware have contributed to medical units, which will allow them to build their own internal production system to make medical devices. Most medical engineers work in the hospitals mainly in charge of maintaining and introducing medical equipment, and the new change will encourage them start to develop their own products. The medical engineer can evaluate possible products to improve the medical quality without the limitation of manufacturing and contribute to a self-sufficient environment.

9.5 Openness

This research not only solves a technical issue in healthcare service but also provides opportunities for clinicians and engineers involved in the related applications. The social interaction between the framework members is another interesting phenomenon in this research, and changes in their relationships and roles can be good indicators of the collaboration progress.

Therefore, I would like to use Actor-Network Theory and Translation steps to explain these changes and their meanings to the actors [103-105]. As the professional who has the necessary technological expertise on this technical issue, the medical engineer is the initial organizer who can start this collaborative network, and undoubtedly, clinicians are the most important stakeholders in this network. When applications of digital fabrication technology extend to medical categories, they attract many clinical practitioners' interest. However, when the related research reveals various approaches to making medical device using a digitalized method, it also deepens the technical gap for clinicians and visibly forms the first stage of the translation process, which is problematization. This occurs because those approaches required deep CAD operation and can only be proceeded by skilled CAD users.

Then, this research revealed the possibility that clinicians could perform the device design by the special digital tool, and this attracts the clinician's interest. This the second stage, interessement, and the digital design tool is an ideal "device" that works for clinicians to become partners in the engineer's network [106,107]. The digital design tool is evolving in this cooperative work and eventually became the critical factor for the last stage, which is Mobilization. In our experiments, when we proved the design tool works for clinicians on device designing for their treatments, the network became closer and stronger.

I used the topic of Experiment 1 as an open source for approximately one year. The method and results was published in the Journal of 3-D Printing in Medicine[6], and I received much feedback and many code requests from interested clinicians and medical engineers globally. They wanted to evaluate the code and generated devices or rewrote the code by themselves. Currently, I have a group on Facebook, and after filtering a few requesters with whom I am familiar, I opened the code to them and am tracking the following applications and modifications. In the process of providing open access to the code, several frequent issues related to open source happened, and I want to share my thoughts here.

[6] Please check List of Publication in end page.

Open for medical study

Although some main evaluations have been proposed in the experiment, I expect that when the code is opened for further quantitative studies by licensed clinicians and medical engineers, this will ensure that possible flaws are discovered. For some clinicians who intend to use the code to generate splints for real treatment, they should ensure the feasible level and safety of the code and the generated devices by themselves.

Modify code under conditions

This code can be modified to suit other medical treatment, but the modified code should be developed collaboratively by a licensed clinician and medical engineer who is proficient with the Grasshopper plug-in and 3-D printing. The modifiers need to evaluate the code and its generated devices through FEA and test the devices carefully for comfort because code rewriting may cause unexpected changes in data flow or undetectable changes in the generated devices. As shown in Fig. 9.5, a modified version was developed for splinting of the lower limb, but as the splint may take higher impact from the feet, the algorithm of optimized thickness, lattice structure, and strength need to be revised.

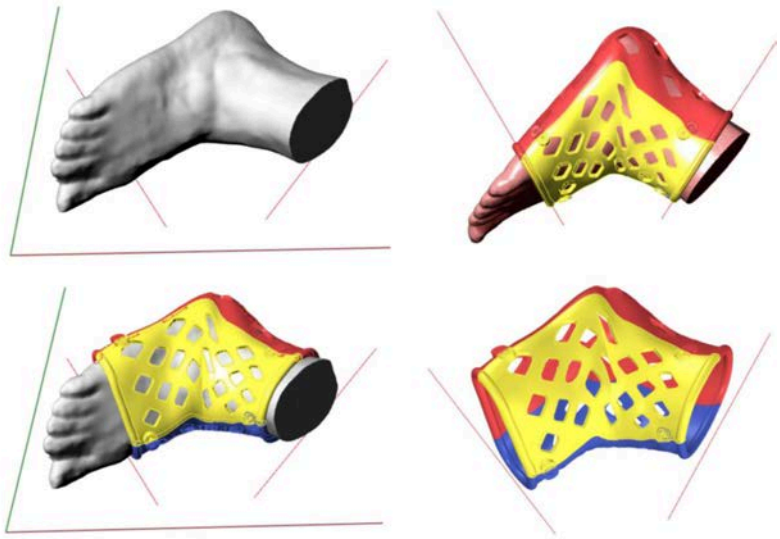


Fig. 9.5 Modified version of splinting device design tool. The version is developed for generating ankle brace.

Maintenance

Many program errors and suggestions for improving the interface have been reported from tester feedback in the group platform and that has generated many updated versions. The application of GitHub or a similar platform is needed to administrate the versions, and an administrative team for evaluating and permitting derivative versions is required.

Concerns of business sale

Because the code and training content can help clinicians to design and make fracture splints independently, it offers the potential to provide benefits to business. Although the code can be attributed under Creative Commons License for a noncommercial purpose, it is difficult to limit people from packaging the code as a commercial CAD software for sale.

Reference

[1] Gershenfeld N. (2005) FAB: The Coming Revolution On Your Desktop - From Personal Computers to Personal Fabrication. New York: Basic Books.

[2] Gershenfeld N. (2012) How to Make Almost Anything: The Digital Fabrication Revolution", J Foreign Affairs, 91(6):43-57.

[3] 田中 浩也 (2012) FabLife—デジタルファブリケーションから生まれる「つくりかたの未 来」, オライリージャパン: book.

[4] Morris J. (2007) The prototype is the product: exploring personal fabrication though a product design project. Proceedings of E&PDE 2007, the 9th International Conference on Engineering and Product Design Education, University of Northumbria, Newcastle, UK, 13.-14.09.2007159-64.

[5] Hermans G. (2015) Opening Up Design: Engaging the Layperson in the Design of Everyday Products. PhD dissertation.

[6] Boyd AS, Benjamin HJ, Asplund C. (2009) Principles of casting and splinting. American Family Physician J. 79(1):16-22.

[7] Volpp KG, Kumholz H, Asch DA.(2018) Mass Customization for Population Health.JAMA Cardiol. 2018;3(5):363-364..

[8] Tseng M, Wang Y, Jiao R. (2017) Mass Customization. Book: CIRP Encyclopedia of Production EngineeringPublisher: Springer, Berlin, Heidelberg. https://doi.org/10.1007/978-3-642-35950-7_16701-3.

[9] Lusardi MM, Jorge M, Nielsen CC. Orthotics and Prosthetics in Rehabilitation. 2nd editio. Oxford: Elsevier; 2007.

[10] Chen RK, Chen L, Tai B, Wang Y, Shih A. (2014) Additive manufacturing of personalized ankle-foot orthosis.

[11] Kelly S, Paterson AM, Bibb RJ, Campbell RI. (2015) Innovations With 3-Dimensional Printing in Physical Medicine and Rehabilitation: A Review of the Literature. J PM&R 8(12):1201-12.

[12] Rengier F, Mehndiratta A, TenggKobligk H, Zechmann CM, Unterhinninghofen R, Giesel FL. (2010) 3D printing based on imaging data: review of medical applications. Int J Computer Assisted Radiology and Surgery. 5(4):335-341.

[13] Portnova AA, Mukherjee G, Peters KM, Yamane A, Steele KM. (2018) Design of a 3D-printed, open-source wrist-driven orthosis for individuals with spinal cord injury, J PLoS ONE, 13(2):e0193106.

[14] Chen RK, Jin Y, Wensman J, Shih A. (2016) Additive manufacturing of custom orthoses and prostheses—A review. J Additive Manufac. 12(A):77–89.

[15] Kate J, Smit G, Breedveld P. (2017) 3D-printed upper limb prostheses: a review. Journal Disability and Rehabilitation: Assistive Technology. 12(3):300-314. doi: 10.1080/17483107.2016.1253117.

[16] Lunsford C, Grindle G, Salatin B, Dicianno BE. (2016) Innovations with 3-dimensional printing in physical medicine and rehabilitation: A review of the literature. PM&R J, 8(12):1201–12.

[17] Paterson AM, Donnison E, Bibb J, Campbell I.(2010) A review of existing anatomical data capture methods to support the mass customization of wrist splints. Virtual and Physical Prototyping J, 5(4): 201-07.

[18] Kelly, S., Paterson, A. and Bibb, R (2015) A review of wrist splint designs for additive manufacture. Proceedings of 14th Rapid Design, Prototyping and Manufacture conference, Loughborough, Great Britain, 15-16.

[19] Dodziuk H. (2016) Applications of 3D printing in healthcare. Polish Journal of THoracic and Cardiovascular Surgery. 13 (3): 283-293.

[20] Zuniga J, Katsavelis D, Peck J (2015) Cyborg beast: a low- cost 3d-printed prosthetic hand for children with upper limb differences. J BMC Res. 2015;8:10.

[21] Strömshed E. (2016) The Perfect Fit Development process for the use of 3D technology in the manufacturing of custom-made prosthetic arm sockets. Master thesis, Lund University.

[22]竹腰美夏, 小林義明, 馬場哲晃. (2016) Metacast：治療用装具における3Dモデルデータ 作成支援システムの提案, Technical report. http://minatsutakekoshi.strikingly.com/blog/metacast

[23] Paterson AM, Donnison E, Bibb J, Campbell I. (2014) Computer-aided design to support fabrication of wrist splints using 3D printing: A feasibility study. Journal Hand Therapy. 19(4):102-113.

[24] Mavroidis C, Ranky RG, Sivak ML, Patritti BL, DiPisa J, Caddle A, Gilhooly K, Govonil J. (2011) Patient specific ankle-foot orthoses using rapid prototyping. Journal of NeuroEngineering and Rehabilitation. 2011;8:1.

[25] Munhoz R, Moraes C, Tanaka K (2016) A digital approach for design and fabrication by rapid prototyping of orthosis for developmental dysplasia of the hip. J Res Biomed Eng. 329(1):63–73.

[26] Shih A, Park DW, Yang YY, Chisena R, Wu D. (2017) Cloud-based Design and Additive Manufacturing of Custom Orthoses. Procedia CIRP. 2017(63):156–60. https://doi.org/10.1016/j.procir.2017.03.355

[27] Zhang X, Fang G, Dai C, Verlinden J, Wu J, Whiting E, Wang CL. (2017) Thermal-comfort design of personalized casts. Proceedings of 30th Annual ACM Symposium on User Interface Software and Technology, Québec City, Canada, 243–54.

[28] Fitzpatrick AP, Mohanned M, Collins PK, Gibson I. (2017) Design of a Patient Specific, 3D printed Arm Cast. KnE Engineering, Conference Proceedings: The International Conference on Design and Technology 2017. 135-42.

[29] Lin H, Shi L, Wang D. (2016) A rapid and intelligent designing technique for patient-specific and 3D-printed orthopedic cast. 3D Print Med J. 2016;2:4.

[30] Baronio G, Harran S, Signoroni A (2016) A critical analysis of a hand orthosis reverse engineering and 3D printing process. Applied Bionics & Biomechanics J. 2016:8347478.

[31] Cha YH, Lee KH, Ryu HJ, Joo IW, Seo A, Kim DH, Kim SJ(2017). Ankle-Foot Orthosis Made by 3D Printing Technique and Automated Design Software. Applied Bionics & Biomechanics J. 2017;2017:9610468.

[32] Poortinga I. (2016) Local fabrication of a custom-fit finger splint. Master Thesis, Univeristy of Groningen.

[33] Walbran M,Turner K, McDaid A. (2016) Customized 3D printed ankle-foot orthosis with adaptable carbon fibre composite spring joint. J.Cogent Engineering. 3(1). DOI: 10.1080/23311916.2016.1227022

[34] Pallari P, Dalgarno KW, Munguia J, Muraru L, Peeraer L, Telfer S, Woodburn J. (2010) Design and additive fabrication of foot and ankle-foot orthoses. in Proceedings of the 21st Annual International Solid Freeform Fabrication Symposium–An Additive Manufacturing Conference, Austin, Texas, USA. 834-45.

[35] Liacouras, Peter C. Sahajwalla, Divya Beachler, Mark D. Sleeman, Todd Ho, Vincent B. Lichtenberger, John P. (2017) Using computed tomography and 3D printing to construct custom prosthetics attachments and devices. 3D Print Med J. 2017;3:8.

[36] Telfer S, Pallari J, Munguia J, Dalgarno K, McGeough M, Woodburn J. (2012) Embracing additive manufacture: Implications for foot and ankle orthosis design. Journal of BMC Musculoskeletal Disorders.13(1):84.

[37] Lim YE, Kim NH, Choi HJ, Park K. (2017) Design for additive manufacturing of customized cast with porous shell structures. Journal of Mechanical Science and Technology. 31(11): 5477-83.

[38] Mohammed M, Cadd B, Peart G, Gibson I (2018) Augmented patient-specific facial prosthesis production using medical imaging modelling and 3D printing technologies for improved patient outcomes. J Virtual and Physical Prototyping. 13(3):164-76.

[39] Li L, Yang LF, Yu F, Shi JP, Zhu L, Yang XF, Teng HJ, Wang XS, Jiang Q (2018) 3D printing individualized heel cup for improving the self-reported pain of plantar fasciitis. Journal of Translational Medicine. 2018(16):167.

[40] U.S. Food & Drug Administration. (2017) Technical Considerations for Additive Manufactured Medical Devices - Guidance for Industry and Food and Drug Administration Staff.

[41] 日本厚生労動省(2015)患者の画像データを用いた三次元積層造形技術によるカスタムメイド整形外科用インプラント等に関する評価指標 (案)

(2015/9/25). http://dmd.nihs.go.jp/jisedai/tsuuchi/薬食機参発0925第1号別紙3.pdf

[42] 日本厚生労働省(2014) 三次元積層技術を活用した整形外科用インプラントに関する評価指標(案) (2014/4/15).http://search.e-gov.go.jp/servlet/PcmFileDownload?seqNo=0000117726

[43] Wear JO. (2008) Certification of Biomedical Engineering Technicians and Clinical Engineers: Important or Not. 7th Asian-Pacific Conference on Medical and Biological Engineering. (19):558-61.

[44] Biomedical Engineering Society, Biomedical Engineer Credentials and Certifications. Article, Accessed 16 July 2018. https://www.healthcarepathway.com/certification/biomedical-engineer-certification.html.

[45] Renno F, Papa S. (2015) Direct modeling approach to improve virtual prototyping and FEM analyses of bicycle frames. Engineering Letters J. 23(4):333–41.

[46] Fu L, Kara LB, Shimada K. Feature.(2012) Future, design intention and constraint preservation for direct modeling of 3D freeform surfaces. J 3D Res. 2012;3:3.

[47] Tornincasa S, Monaco F.(2010) The future and the evolution of CAD. 14th International Research/Expert Conference: Trends in the Development of Machinery and Associated Technology, 2010.

[48] Hamilton P.(2013) Parametric modeling vs. direct modeling. http://www.metalformingmagazine.com/assets/issue/pdf/diedesign2013/direct_vs_parametric.pdf . Accessed 30 May 2017.

[49] Harding JE, Shepherd P. (2017) Meta-parametric design. Design Studies J. 52: 73–95.

[50] Krish S. (2011) A practical generative design method. CAD J. 43(1):88–100.

[51] Aish R. (2017) Comparative evaluation of parametric design systems for teaching design computation. Design Studies J. 52:144-72.

[52] Clean G, Eduardo C, Vaz V. (2012) CAD scripting and visual programming languages for implementing computational design concepts: a comparison from a pedagogical point of view. Architectural Computing Int J. 10(1):121-38.

[53] Leitão A, Santos L, Lopes J. (2012) . Programming languages for generative design: a comparative study. Architectural Computing Int J. 10(1):139-62.

[54] Nelson, H. G., & Stolterman, E. (2012). The Design Way: Intentional Change in a Unpredictable World (2nd ed.). The MIT Press.

[55] Ostuzzi F, Couvreur LD, Detand J, Saldien J. (2017) From Design for One to Open-ended Design. Experiments on understanding how to open-up contextual design solutions. Design Journal. 20(1):3873-83.

[56] Hermans G. (2014) Investigating the Unexplored Possibilities of Digital–Physical Toolkits in Lay Design, IJD. 8(2):15-28.

[57] Ventral C. (2014) Medical applications for 3D printing: current and projected uses. P&T J. 39(10):704-11.

[58] Rayna T, Striukova L, Darlington J.(2015) Co-creation and user innovation: The role of online 3D printing platforms. J Eng & Tech Mag. 37:90-102.

[59] 青木翔平 (2015) Design Support for Creative Problem Solving in Developing Countries Design Support for Creative Problem Solving. PhD thesis, Department of Aeronautics and astronautics, University of Tokyo.

[60] Hermans G, Valtonen A. (2014) Investigating the Changing Relation between Consumer and Designer in Post-Industrial Design. DRS 2014. Umeå, Sweden: Umeå University.

[61] Activarmor, a custom-made splint developed by ActivArmour company in United States, http://activarmor.com

[62] Zdravprint, a 3-D printed cast developed by Russian company, Zdravprint, http://zdravprint.ru

[63] XKELET, a 3-D printed splint developed by XKELET company, https://www.xkelet.com

[63] CORTEX, a 3-D printed splint designed by Jake Evill in 2013 http://www.evilldesign.com/cortex

[65] Osteoid Medical cast designed by Denis Karasahin in 2014, http://www.osteoid.com

[66] Cason A, Kelly S, Paterson AM, Bibb R, Camel IR.(2017) Analysis and comparison of wrist splint designs using the finite element method: Multi-material three-dimensional printing compared to typical existing practice with thermoplastics. Eng in Med J, 231(9):881-97.

[67] Faria A (2017) Additive manufacturing of custom-fit orthoses for the upper limb. Master Thesis. Department of Engineering and Technology. University of Porto. http://hdl.handle.net/10216/103720.

[68] Amiri A, Varghese J, Demurchyan G.(2017) Toward in-situ realization of ergonomic hand/arm orthosis, a pilot study on the process and practical challenges. Technical Report of Politecnico di Milano. https://doi.org/10.13140/RG.2.2.18381.84968

[69] Fitch MT, Nicks BA, Pariyadath M, McGinnis HD, Manthey DE. (2008) Basic Splinting Techniques. N Engl J Med. 359:e32.

[70] Chen YJ, Lin H, Zhang X, Huang W, Shi L, Wang D.(2017) Application of 3D–printed and patient-specific cast for the treatment of distal radius fractures: initial experience. 3DP in Med J. 2017(3):11.

[71] Paterson AM, Bibb RJ, Campbell RI. (2012) Evaluation of a digitised splinting approach with multiple-material functionality using Additive Manufacturing technologies. Proceedings of the Solid Freeform Fabrication Symposium. 2012: 656-72.

[72] Kim H, Jeong S (2015) Case study: Hybrid model for the customized wrist orthosis using 3D printing. J Mech Sci Technol 29(12):5151–6.

[73] Personalized 3D splint, Exovite, http://www.exovite.com/en/exovite-en/

[74] Negi S, Dhiman S, Sharma RK. (2014) Basics and applications of rapid prototyping medical models. Rapid Prototyping J. 20(3):256–67.

[75] Milusheva SM, Tosheva EY, Kouzmanov LV, Zlatov N, Toshev YE. (2006) Personalised ankle–foot orthoses design based on reverse engineering. Proceedings of the 5th Virtual International Conference on Intelligent Production Machines and Systems, 2016:12–14.

[76] Bonarrigo F, Signoroni A, Botsch M. (2014) Deformable registration using patch-wise shape matching. Graphical Models J. 76(5):554–65.

[77] Bonarrigo F, Signoroni A, Leonardi R. (2012) Multi-view alignment with database of features for an improved usage of high-end 3D scanners. J Adv Signal Process. 2012:148.

[78] Paterson AM, Bibb RJ, Campbell RI, Bingham G (2015) Comparing additive manufacturing technologies for customised wrist splints. Rapid Prototyping J. 21(3):230–43.

[79] Palousek D, Rosicky J, Koutny D, Stoklásek P, Navrat T. (2014) Pilot study of the wrist orthosis design process. Rapid Prototyping J 20(1):27–32.

[80] Bibb R, Freeman P, Brown R, Sugar A, Evans P, Bocca A. (2000) An investigation of three-dimensional scanning of human body surfaces and its use in the design and manufacture of prostheses. Eng in Med J. 214(6):589–94.

[81] Rengasamy S, King WP, Eimer BC, Shaffer RE. Filtration performance of NIOSH-approved N95 and P100 filtering facepiece respirators against 4 to 30 nanometer-size nanoparticles. Journal of Occupational and Environmental Hygiene. 2008(5): 556-64.

[82] Eshbaugh JP, Gardner PD, Richardson AW, Hofacre KC. (2009) N95 and p100 respirator filter efficiency under high constant and cyclic flow. Journal of Occupational and Environmental Hygiene 2009(6): 52-61.

[83] He X, Grinshpun SA, Reponen T, Yermakov M, McKay R, Haruta H, Kimura K. (2013) Laboratory evaluation of the particle size effect on the performance of an elastomeric half-mask respirator against ultrafine combustion particles. The Annals of Occupational Hygience. 2013(57): 884-97.

[84] Coffey CC, Campbell DL, Zhuang Z. (1999) Simulated workplace performance of N95 respirators. American Industrial Hygiene Association Journal. 1999(60): 618-24.

[85] Campbell DL, Coffey CC, Lenhart S.(2001) Respiratory protection as a function of respirator fitting characteristics and fit test accuracy. AIHAJ - American Industrial Hygiene Association. 2001(62): 36-44.

[86] Coffey CC, Lawrence RB, Campbell DL, Zhuang Z, Calvert CA, Jensen PA. (2004) Fitting characteristics of eighteen N95 filtering- facepiece respirators. Journal of Occupational and Environmental Hygiene. 2004(1): 262-71.

[87] Lawrence RB, Duling MG, Calvert CA, Coffey CC. (2006) Comparison of performance of three different types of respiratory protection devices. Journal of Occupational and Environmental Hygiene. 2006(3): 465-74.

[88] U.S. OSHA. Respiratory protection standard (29 CFR 1910.134); 1998.

[89] 社団法人日本保安用品協会JSAA, 財団法人日本規格協会 JSA. (2006) JIST 8159:2006 呼吸用保護具の漏れ率試験方法. http://kikakurui.com/t8/T8159-2006-01.html

[90] 職業感染制御研究会 (2012) 医療従事者のための N95マスク適正使用ガイド.

[91] Chen, CW., Chang, CH., Yang, SJ., Huang, SH.(2008) The Study on Fit Test Procedure of N95 Filtering Facepiece Respirators. Journal of Occupational Safety and Health. 2008(16): 304-14.

[92] Chen, CW., Huang, SH.(2013) Study on the Strategy of Respirators Selection and Management. Technical report, ISBN：978-986-04-4636-4.

[93]Chang CH, Yang SJ, Huang SH, Chang CH, Chen CW.(2006) Fitting Characteristics of Filtering Facepiece Respirator for Health Care Workers. Journal of Occupational Safety and Health. 1(4): 262-71.

[94] Slicer software, Simplify 3D 4.0, https://www.simplify3d.com

[95] Hung SH, Hsu CW, Kuo WC, Chen CW, Chen CC.(2016) A Study on the Feasibility of Conducting Qualitative Fit Test by Using Pneumatic Medical Nebulizers. Journal of Labor, Occupational Safety and Health 24: 213-236.

[96] Mullins HE, Danisch SG, Johnston AR.Development of a new qualitative test for fit testing respirators. American Industrial Hygiene Association Journal. 1995(56): 1068-73.

[97] Han DH, Willeke K, Colton CE. (1997) Quantitative fit testing techniques and regulations for tight-fitting respirators: current methods measuring aerosol or air leakage, and new developments. American Industrial Hygiene Association Journal. 1997(58): 219-28.

[98] NIOSH. (2013) Framework for Setting the NIOSH PPT Program Action Plan for Healthcare Worker Personal Protective Equipment: 2013-2018, draft, Version 7 June 2013.

[99] IOM. (2008) Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers. Washington, DC: The National Academies Press.

[100] 3M. Qualitative Fit Test.(2005) Accessed August 23,2017 (http://multimedia. 3m.com/ mws/mediawebserver?6666660Zjcf6lVs6EV s666qg9COrrrrQ-).

[101] TSI. Respirator Fit Testers.(2012) (Accessed September 1, 2017) http:// www.tsi.com/uploadedFiles/_ Site_Root/Products/Literature/Manu als/Q-Fit-Manual.pdf.

[102] Niezen G, Eslambolchilar P, Thimbleby.(2016) Open-source hardware for medical devices. BMJ J.2(2):78-83.

[103] Callon M. (1984) Some elements of a sociology of translation: domestication of the scallops and the fishermen of St Brieuc Bay, 32(1):196-233.

[104] Gherardi S, Nicolini D.(2005) Actor-networks: Ecology and Entrepreneurs, Book. Actor-Network Theory and Organizing, Copenhagen : Copenhagen Business School Press, 285-306.

[105] Yaneva A.(2009) Making the Social Hold: Towards an Actor-Network Theory of Design, The Journal of the Design Studies Forum. 1(3):273-88.

[106] Akrich M.(2002) The key to successs in innovation part 1: the art of interessement, Int.J.Innov, 6(2):187-206.

[107] Callon M.(1999) Actor-network theory the market test, J. Sociological Review, 1999.https://doi.org/10.1111/j.1467-954X.1999.tb03488.x

List of Publications

Journal papers

[1] Jianyou Li and Hiroya Tanaka,” Feasibility study applying a parametric model as the design generator for 3D–printed orthosis for fracture immobilization”, Journal of 3D Printing in Medicine, 2018;4:1.

[2] Jianyou Li and Hiroya Tanaka,” Rapid customization system for 3D-printed splint using programmable modeling technique – a practical approach”, Journal of 3D Printing in Medicine, 2018;4:5.

Conference papers

[1] Jianyou Li and Hiroya Tanaka,”Openness approaches of product design in the digital fabrication”**,** International Conference of Digital Fabrication, Tokyo, 2015.

[2] Jianyou Li and Hiroya Tanaka,” The flexibility controlling study for 3D printed splint “, Conference SPIE 2017, Portland, Oregan, US.

[3] Jianyou Li, Hiroya Tanaka and Shoko Miyagawa,” Applying the programmable modeling tool to support the hospital infection control staff in customizing the filtering face-piece respirators for healthcare worker”, 9th International Conference on Applied Human Factors and Ergonomics and the Affiliated Conferences, Orlando, Florida, U.S , 2018.